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“Down Your Drink” (DYD). A Digital Intervention to Reduce Harmful Drinking

A thesis submitted to Middlesex University  
in partial fulfilment of the requirements for the degree of  
PhD by Public Works

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# “Down Your Drink” (DYD). A Digital Intervention to Reduce Harmful Drinking

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## Abstract

Excessive alcohol consumption contributes to significant individual and societal harms. Screening and Brief Interventions are effective in reducing consumption and digital versions, delivered online, have the potential to reach large numbers of people, who would not otherwise receive help, at low marginal costs.

Downyourdrink (DYD) is a digital intervention based on Cognitive Behaviour Therapy, Motivational Interviewing and Social and Behaviour Network Therapy. DYD was evaluated using the Medical Research Council’s framework for complex interventions. Several studies showed that large numbers of users registered with the programme and were willing to provide data, but levels of attrition were high. Users were largely in their mid to late thirties, half were female, just over a third were single, nearly half lived with children and they were predominantly white British and of higher socioeconomic status. An online pragmatic randomised controlled trial found that weekly alcohol consumption reduced by 20 standard units, but there was no advantage for the group that had access to DYD. These results are discussed in relation to findings from other studies, methodological issues raised by online research and the common finding that control groups in alcohol studies reduce consumption following baseline assessments.

Implementation trials were conducted in different health, occupational and community settings. Mixed methods studies and process evaluations examined the challenges encountered in each of these settings. Conceptual models, such as that of Freeman and Sturdy (2014), were used to identify different types of

knowledge involved in developing interventions and policy frameworks that enable successful deployment.

The direction of DYD's development was determined by overlapping contexts. Research funding through health and university bodies required adherence to a scientific framework. Public services set goals for the reduction of harms, equity of access and the efficient use of resources. The personal context included professional development, values and interests.

## CONTENTS

<b>Abstract</b>	<b>2</b>	
<b>Table of Contents</b>	<b>4</b>	
<b>List of Tables</b>		
Table 1	Drinking frequency in the week before interview, by sex and age, England, 2005-2016	<b>54</b>
Table 2.	Hypothesised Key Characteristics of Visitors To “Downyourdrink”	<b>74</b>
Table 3	Hypothesised Experiences of Visitors To “Downyourdrink”	<b>75</b>
Table 4	Activity on DYD website 2014-2017	<b>78</b>
<b>List of Figures</b>		
Figure 1	Timeline of the Development of "Down Your Drink	<b>17</b>
Figure 2	Abstract - <i>Internet-Based Methods in Managing Alcohol Misuse</i>	<b>61</b>
Figure 3	The Down Your Drink Family Tree	<b>103</b>
<b>Acknowledgements</b>	<b>8</b>	
<b>Introductory Personal Statement</b>	<b>9</b>	
<b>Aims</b>	<b>10</b>	

<b>List of Public Works</b>	<b>12</b>
Publications	
Manual and Websites	
Conference Presentation	
Additional related publications	
<b>Timeline</b>	<b>17</b>
<b>Chapter One The story of “Down your Drink”</b>	<b>18</b>
Pontefract (West Yorkshire)	
Alcohol Services Pontefract and Wakefield	
Islington Psychology Service, Friends and Family	
The first research grants	
Developing the site	
Developing the Questions and Building a Team.	
Designing and implementing the trial	
Dissemination	
Kingston PCT	
Workplaces	
Redevelopment	
Current research directions	
Theoretical Analysis of Implementation	
<b>Chapter Two Background</b>	<b>48</b>
Introduction	
Definitions	
Consumption	
Treatment for Alcohol Use Disorders – theory and practice	

Screening and Brief Interventions  
Digital Behaviour Change Interventions  
Conclusions

**Chapter Three    Methods** **66**

Introduction  
The methodology to develop the intervention  
Implementation  
Evaluation

**Chapter Four    Results** **71**

Introduction  
Development and pilot studies of “Down Your Drink”  
Cohort Study  
The optimised version of “Down Your Drink”  
Evaluation Studies  
Implementation Studies

**Chapter Five    Discussion** **92**

Introduction  
The Science Context  
The Public Service Context  
Personal factors as context  
Conclusions  
What next for Digital SBIs?

**Afterword** **110**

<b>References</b>	<b>111</b>
<b>Appendices</b>	<b>122</b>
Appendix 1	Sample pages from the original printed manual
Appendix 2	Examples of the first interactive version (DYD <sub>1</sub> )
Appendix 3	Sample Press Releases and publicity material
Appendix 4	The Content of DYD <sub>1</sub>
Appendix 5	Home Page of the “psychologically enhanced” version
Appendix 6	The Current Homepage of Down Your Drink
Appendix 7	HeLP Alcohol (DYD <sub>4</sub> )
Appendix 8	Healthier Drinking Choices UK and Australia
Appendix 9	Drinking Choices for Better Mental Health
<b>Public Works</b>	<b>138</b>



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My thanks go to my collaborators in the eHealth unit at UCL and elsewhere – particularly Paul Wallace, Elizabeth Murray and Zarnie Khadjesari - who all contributed enormously to this research.

Richard McGregor of *Codeface* built and maintained all the different versions of the intervention and research websites. I am grateful for his technical skills, creative flair and endless patience.

This work was part funded by research grants from Alcohol Concern, the Alcohol Education Research Council, North Central London Research (NoCLoR) and the National Prevention Research Initiative. These grants paid for the direct costs of building the interventions, but for only a small amount of my time. This project would not have been accomplished without the support of my NHS managers and colleagues who had the breadth of vision to see the potential of the work and the value of innovation.

Writing grant applications and academic papers takes time and was largely done outside of normal office hours. The same was true of this contextual statement. I am enormously grateful to my wife Jenny for her support and encouragement throughout and to my children Yossi and Miri for their tolerance of a distracted and busy member of the household.

Thanks are also due to Rachel Herring and Betsy Thom – my PhD supervisors – who have been encouraging and attentive and introduced me to new ideas that helped me to see my work as a whole and set it in its broader context.

## **Introductory Personal Statement.**

Alcohol is the world's third largest risk factor for disease; it is the leading risk factor in the Western Pacific and the Americas and the second largest in Europe. Alcohol use results in approximately 2.5 million deaths each year (Fleischmann et al., 2011). In the United Kingdom, in 2016, 9.6% of the population reported drinking on 5 days or more in the previous week and 7.8 million people "binged"<sup>1</sup> on their heaviest drinking day (Office for National Statistics, 2017). In 2015 it was estimated that 1.4% of all deaths were related to the consumption of alcohol and there were 1.1 million hospital admissions (NHS Digital, 2017).<sup>2</sup> In England according to the Alcohol Use Disorders Identification Test (AUDIT), 16.6% of adults drank at hazardous levels, 1.9% were harmful or mildly dependent drinkers and 1.2% were probably dependent drinkers (Adult Psychiatric Morbidity Survey, chapter 10, 2014). Public Health England (2016) reported studies that estimated the health, social and economic costs associated with alcohol use to be £47bn or 2.5% of GDP.

There is a long history of negative public attitudes towards the problems caused by alcohol. The common picture has been that of the drunkard or inebriate in need of help or reform. The victims were often perceived as weak or moral failures. In modern times they may be viewed as ill and requiring treatment. The statistics quoted above tell a different story; that of a significant public health problem which burdens not just individuals, but society and our social institutions. Although some people are dependent on alcohol the societal impact is experienced by those who drink above safe levels and by those around them. The interventions described in this work are directed towards harmful and hazardous drinkers.

In my contextual statement I present research aims, a literature review, theory, methods and results; but I also offer a narrative that describes key events which were influential in

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1 Binge drinking is defined as males who exceeded 8 units of alcohol on their heaviest drinking day, and females who exceeded 6 units on their heaviest drinking day.

2 <https://digital.nhs.uk/catalogue/PUB23940> (accessed 13/4/2018)

the developing “story”. For a successful project a combination of good science, good management and good “luck” are required. “Down your Drink” (DYD) has been a thirty-year project (see fig 1). Its development has been closely intertwined with my own career pathway and sets of circumstances that led me to be “in the right place at the right time” for the project to take root and develop. I hope that the current work conveys this journey. For the purposes of clarity I have attempted to section the work conventionally into chapters on background, methods, results, discussion etc; this was difficult to do whilst maintaining the narrative flow. I have placed my reflections and discussions after each stage of the work rather than keeping them all for the end. The theoretical grounding for DYD (the alcohol treatment/intervention theory) is described in chapter two as part of the literature review, the research model is in chapter three and the theoretical analysis of the overall project is in chapter one and reprised in my conclusions in the final chapter.

The story as I present it places my own role at the centre. There could be other versions. I describe events as if I were an actor with control over what happened, responding to circumstances with a plan or intention. In retrospect I can see that, while my academic and clinical training were highly influential, my experience of the work at the time was different. The steps in the journey felt opportunistic and unplanned. My awareness of specific motivations was limited, and I often relied on a gut feeling for what the next step should be and learned from the reactions of others around me. In writing this contextual statement I have come to see and reflect on some of the factors that greatly influenced my actions and the project overall.

## **AIMS**

### Aims of the Research Programme

#### Primary aims:

1. To assess the feasibility and acceptability of an evidence based digital online extended brief intervention for hazardous and harmful drinkers
2. To describe
  - a. the level of recruitment to the intervention, engagement and activity on the website
  - b. The demographic characteristics of the users
3. To undertake a series of studies evaluating the use and effectiveness of the intervention in a range of settings

#### Secondary aims:

1. To contribute to the knowledge base of conducting research online
2. To contribute to the knowledge base of the performance of online interventions and their place in healthcare pathways

### Aims of the Contextual Statement

1. To provide an account that gives complementary interwoven contexts for the research:
  - a. The science context
  - b. The public services context
  - c. The personal context
2. To draw conclusions about the main findings, the impact of these contexts and propose directions for future research and development.

## List of Public Works

### Publications

1. **Linke, S.B.** (1989) "Down Your Drink" - a self-help manual for problem drinkers *Alcohol Concern*, Vol 5(1), 9-10
2. **Linke** (2003) Down your drink: an online treatment programme for problem drinkers. *Alcohol Insight* 18 March
3. **Linke, S.**, Brown, A and Wallace, P. (2004) Down Your Drink: A Web-based Intervention for People with Excessive Alcohol Consumption. *Alcohol and Alcoholism* Vol 39, No 1, pp 29-32

I wrote publications 2 and 3 with Paul Wallace's support. Andrew Brown was a part time research assistant who collated the pilot data on excel spreadsheets and performed the calculations.

4. **Linke, S.**, Murray, E., Butler, C and Wallace, P. Internet-Based Interactive Health Intervention for the Promotion of Sensible Drinking: Patterns of Use and Potential Impact on Members of the General Public *J Med Internet Res* 2007; 9 (2)

Elizabeth Murray invited me to join the eHealth unit at University College London and she suggested that I publish this cohort data. Ceri Butler did the initial liaison with the computer programmer to download the data. I retrieved and analysed the data on the SQL database and wrote the paper.

5. **Linke S**, McCambridge J, Khadjesari Z, Wallace P, Murray E (2008) Development of a psychologically enhanced interactive online intervention for hazardous drinking. *Alcohol Alcoholism* 43(6): 669–74.

I wrote the paper and led the team that redesigned the original Down Your Drink website and was part funded to work on this project for three years. Our roles overlapped considerably as we worked as a team, but the principal responsibilities were as follows:

Stuart Linke – I designed the original programme and restructured it based on the theoretical framework that I had developed. I also designed the online tools and created the information pages and the CBT and SBNT content.

Jim McCambridge – Motivational Interviewing/enhancement content

Zarnie Khadjesari – conducting and analysing the user panels/focus groups and proof reading and editing

Paul Wallace – Trial design and overall management.

Elizabeth Murray – Trial design and checking medical content

6. Wallace P, Murray E, McCambridge J, Khadjesari Z, White IR, Thompson, S, Kalaitzaki, E, Godfrey, C and **Linke, S** (2011) On-line Randomized Controlled Trial of an Internet Based Psychologically Enhanced Intervention for People with Hazardous Alcohol Consumption. *PLoS ONE* 6(3):

In addition to my role leading on the DYD intervention I also had specific responsibilities in the trial design for the mental health outcome measures and the non-interactive control condition. I was involved in developing the online methodology based on the learning from the earlier pilot and cohort studies. This included the overall recruitment strategy, estimating the potential sample size for the power calculations, advising on the practicalities of the stop/go criteria, designing the consent and registration processes, and defining the key components for the sensitivity analyses. In recognition of the breadth of role and of holding the overall vision of the project I was designated as the final (supervising) author.

Ian White, Simon Thompson and Rina Kalaitzaki were the trial statisticians and Christine Godfrey was the Health Economist.

7. **Linke, S.**, Wallace, P. and Harrison, R. (2005) A Web based intervention used in general practice for people with excessive alcohol consumption. *Journal of Telemedicine and Telecare*, 11 (supp 1)

I conducted the two focus groups. Robert Harrison (a medical sociologist) observed, recorded and conducted the initial thematic analysis. Paul Wallace and I validated the themes. I wrote the first draft of this paper and Robert contributed the verbatim reports.

8. Murray, E., **Linke, S.**, Harwood, E., Conroy, S., Stevenson, F., and Godfrey, C. (2012) Widening access to treatment for alcohol misuse: description and formative evaluation of an innovative web-based service in one primary care trust. *Alcohol and Alcoholism*; 47(6):697-701

Elizabeth and I originated and led this study and recruited Elissa Harwood to be the local researcher. The original plan was for Elissa Harwood to write the paper, but she changed jobs and was unable to complete the manuscript before returning home to Australia. Elizabeth took primary responsibility for drafting the paper in her absence.

9. Murray, E, Khadjesari, Z, **Linke, S.** Hunter, R, and Freemantle, N (2013) Health on the web: randomised trial of work-based online screening and brief intervention for hazardous and harmful drinking *BMC Public Health*. 13:505.

In this paper I designed the alcohol component of the intervention, advised and liaised with the health lead in the company.

10. Hamilton, F; Hornby, J; Sheringham, J; **Linke, S**; Ashton, C; Moore, K; Stevenson, F; (2017) DIAMOND (Digital Alcohol Management ON Demand): a mixed methods feasibility RCT and embedded process evaluation of a digital health intervention to reduce hazardous and harmful alcohol use. *Pilot and Feasibility Studies*, 1, Article 28.

In the DIAMOND studies I conducted a major redesign of the site and added new material and case studies. I also commissioned the theatre company wrote the case studies on which the screenplay was based.

11. **Linke, S.** and Murray, E. (2017) Internet-Based methods of managing alcohol misuse. Oxford Research Encyclopaedia of Psychology

#### Manuals and Websites

1. DYD<sub>0</sub> The original printed manual
2. DYD<sub>1</sub> The first online version used for the feasibility and pilot
3. DYD<sub>2</sub> The optimised version used for the trial
4. DYD<sub>3</sub> The publicly available site [www.downyourdrink.org.uk](http://www.downyourdrink.org.uk)
5. “Drinking Choices” suite of sites
6. DYD<sub>4</sub> HeLP Alcohol <http://dyd4.herokuapp.com/>
7. Translated versions of “Down Your Drink” used in the EFAR studies
8. Drinking Choices for Better Mental Health

#### Conference Presentation

Wallace, P. and **Linke, S.** “Ten Years’ Experience with Down Your Drink” Alcohol Research UK (2013) <http://www.fead.org.uk/video/paul-wallace-and-stuart-linke-on-ten-year-experience-with-down-your-drink-dyd/>



### Additional related publications

**Linke, S.** (2012) “Thinking about Drinking: Towards a Safer Relationship with Alcohol.”

Muswell Hill Press ISBN-13 9781908995018

This is a self-help book based on the content of DYD<sub>4</sub>

Wallace, P., **Linke, S.**, Murray, E., McCambridge, J. and Thompson, S. (2006) A Randomized Controlled Trial of an interactive Web-based intervention for reducing alcohol consumption. *Jnl. of Telemedicine and Telehealth (supplement)*, 12, 52-54

Murray, E., McCambridge, J., Khadjesari, Z., White, I., Thompson, S., Godfrey, C., **Linke, S.**, and Wallace, P. (2007) The DYD-RCT protocol: an on-line randomised controlled trial of an interactive computer-based intervention compared with a standard information website to reduce alcohol consumption among hazardous drinkers. *BMC Public Health* 2007, 7:306

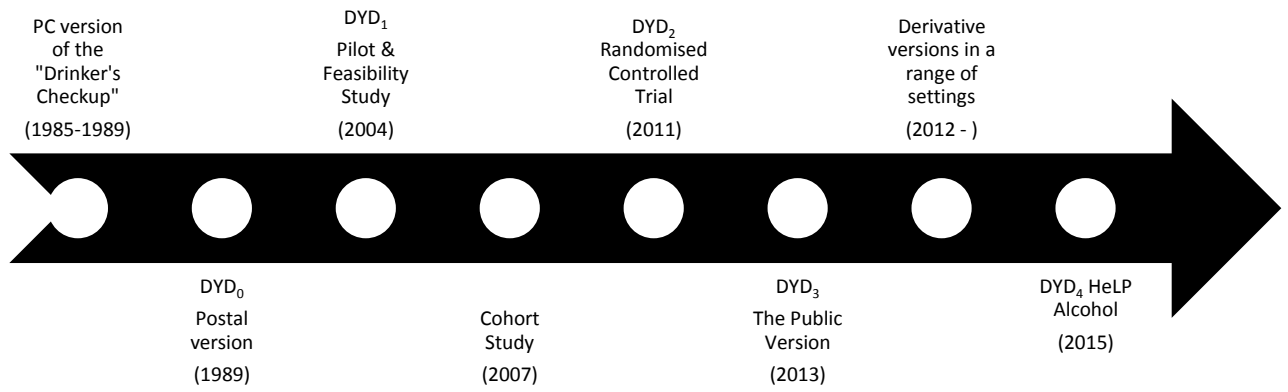
McCambridge J, O'Donnell O, Godfrey C, Khadjesari, Z, Hunter, R, Freemantle, N, **Linke, S.**, Murray, E and Wallace, P. (2010) How big is the elephant in the room? estimated and actual IT costs in an online behaviour change trial. *BMC Res Notes*. 3:172.

McCambridge, J, Kalaitzaki, E, White, IR, Khadjesari, Z, Murray, E, **Linke, S.**, Thompson, SG, Godfrey, C & Wallace, P (2011), 'Impact of length or relevance of questionnaires on attrition in online trials: randomized controlled trial' *JMIR*, vol. 13, no. 4

Khadjedari, Z, Stevenson F, Toner P, **Linke S.**, Milward J, and Murray E (*in press*). “‘I’m not a real boozer’”: a qualitative study of primary care patients’ views on drinking and its consequences’ *Journal of Public Health*.

**Figure 1**

**Timeline of the Development of "Down Your Drink"**



## **CHAPTER ONE      The Story of “Down Your Drink.”**

The background to the work described in this thesis is my continuous employment in the National Health Service (NHS) as a clinical psychologist working in a range of adult mental health settings. Clinical work poses problems that don't always have ready solutions and innovation is required. It is my intention that, by describing some of the situations and challenges I encountered, the project's key drivers and influences will become apparent.

### Pontefract (West Yorkshire) – the creation of a new community alcohol treatment service

In 1981 I qualified as a clinical psychologist and started work at Pontefract General Infirmary (PGI) in West Yorkshire. The psychiatric unit had been recently built on a greenfield site and it was the first time that Pontefract had had its own service. Until then psychiatrists and psychologists had travelled from nearby Wakefield. Pontefract district was a largely rural area with small towns dominated by the coal mining industry, agriculture and the Ferrybridge power station. The dominant culture was that of the “pit villages.” A strong community spirit centred on the miners' working men's clubs, pubs and welfare institutions. From my outsider's perspective heavy drinking appeared to be the norm and strongly linked to the working culture. Although, like many students, I had spent time in the subsidised bar of the student's union, regular heavy drinking was not something I was familiar with and I looked for a way to make sense of it. I developed my own “folk” hypothesis. Coal mining is hard, hot, thirsty work as I found out for myself when I visited the Prince of Wales colliery with a group of community psychiatric nurses from the unit. After a morning underground, during which I accepted the invitation to crawl along a working coal face next to a heavy piece of machinery graphically called a “ripper”, I coughed and sneezed coal dust for several hours. The only thing that would slake my thirst was a pint of draught beer. These were times when there was a culture of drinking at lunchtime during the working week. This may appear to be extraordinary nowadays in the public sector, but at the time it was not only acceptable - but common.

I had applied to Pontefract because of the opportunity to be involved in establishing a new service and the potential to explore my interest in, and commitment to, community approaches. There were only two psychologists in the entire District; myself, and my supervisor/manager Steve. Although our office happened to be in the day hospital of the psychiatric unit, we were responsible for seeing patients from all specialities across the entire range of ages and service groups. Steve was a supportive colleague and teacher. Alongside his technical expertise and skill, however, he also brought something equally valuable and useful – local knowledge. He was from the local area and the son of a miner. It was through his eyes and that I came to understand something of the local culture, social history and the role of heavy drinking.

The Pontefract area, although part of the former West Riding of Yorkshire, was culturally aligned with the coal mining areas of South Yorkshire, particularly Barnsley and Doncaster, and many families and communities were strongly associated with the activities of the National Union of Mineworkers (NUM). My early work in Pontefract was in the period leading up to, during and after the year-long national miners' strike. This was the background to my clinical work and interests. Many of the unit staff were from mining families and during some unrelated industrial action by hospital workers the NUM had unofficially supported picket lines and brought sandwiches ("snap" in the local dialect) and NUM members were often casual visitors to the hospital offices. The normal professional boundaries between staff, patients and visitors were looser than I was used to from my clinical training. This was all unsurprising to Steve. He told me that prior to the opening of the infirmary, the only medical facilities locally were those built by public subscription and attached to the pits. The local community felt that they owned the hospital and were grateful for the medical care it provided. This context was to play its role in the development of the alcohol treatment service based at PGI.

My primary role was to assess and treat patients referred by GPs, Psychiatrists and hospital doctors for a range of mental health problems, but mostly anxiety and depression. I saw patients in the hospital out-patients department and in GP surgeries. The experience of heavy drinking was regularly present in the consulting room, either as

part of a mental health problem or in the stories I heard of heavy drinking in a family member. These individuals were not “addicts” who required admission for detoxification under medical supervision; but heavy drinkers whose consumption was considered normal by people in the local culture. The group I am describing appeared to be similar to the socially stable longstanding regular steady drinkers described in the Birmingham untreated heavy drinkers study (Rolfe, Orford and Martin, 2009). They drank frequently and heavily, had relatively low levels of alcohol dependence, experienced poor health and other harms, used general hospital services more than average (but not GPs) and did not receive professional help for their drinking. Their drinking was socially embedded *“within family and social settings and other activities which are in general approving or accepting of relatively heavy drinking. The pub constituted for many participants a very significant setting in their lives, and provided, for many, a real feeling of community” (pp 15-15).*

The only available alcohol service in the area was a meeting of Alcoholics Anonymous which was held in the Methodist church hall. This was for “addicts” and promoted only abstinence, so I decided to bring together a team of staff to discuss how we might develop our own alcohol service with a different approach.

Whilst a student on the Leeds University Clinical Psychology training course we had been taught about alcohol problems and treatment by psychologists from the Leeds Addictions Unit. I remember their lectures as engaging and informative and I invited Dr Robin Davidson from the unit to run a training session for us at the PGI. He generously agreed, and we held a half-day session for a multidisciplinary group (psychologist, social worker, community psychiatric nurses and a doctor) and we had a follow-up session a few months later. Robin taught about assessment, indicators of dependence, early warning signs of a drinking problem and approaches to treatment. I recall two key research findings that proved to be fundamental to the alcohol treatment service we later developed and crucial to the development of Down Your Drink.

1. Controlled drinking was a viable, practical and effective treatment and often more acceptable than abstinence (Heather and Robertson, 1981).

2. “Two groups of alcoholics received either one counselling session or several months of inpatient and outpatient treatment. One year later there were no significant differences in outcome between the two groups” (Edwards et al, 1977, page 1004).

The discussion that followed led us to a clear conclusion. We needed a local team, integrated with the rest of the unit that was equipped and ready to treat individuals with drinking problems. The team consisted of myself, a doctor, a nurse and a psychiatric social worker. None of us had dedicated time to commit to the service, but we chose to manage our workloads in such a way to make space in our week to do this. Later, after we had some experience with the approach, we were able to obtain funding for a Community Psychiatric Nurse who joined the team and offered a home (community based) detoxification service.

The treatment model we adopted was to provide a one-off intense experience that would facilitate a reflective mode and give the information a person needed to change their drinking if they wished to do so. This was followed by a weekly evening “Problem Drinkers Group” for six weeks facilitated by one of our team. We were persuaded by the research that we had read, and the advice from the Leeds Addictions Unit, that a traditional intensive treatment service was not the best use of our limited resources and also that both controlled drinking and abstinence (based on a medically supervised detox) were valid treatment goals.

The components of the approach were as follows:

- Referral by a member of the mental health team followed by the offer of an assessment date:
- Attendance at the unit for a half day during which they were:
  - Interviewed by a team member to
    - Provide information about the service and given written information about drinking
    - Collect demographic information

- Complete the “Drinkers Check Up” (see below)
    - Have a blood test (specifically a liver function test) and a general medical check up
- Attend for a second appointment
  - Given feedback by a team member based on the “Drinkers check Up” (Miller and Sovereign, 1989) and the doctor’s report
  - Any required medical referrals were made and feedback to the GP
- Attendance at the six-week small “problem drinkers group” for education, problem solving and social support.

The “Drinker’s Check-up” was a hybrid combination of assessment and feedback based on Motivational Interviewing principles. We adopted an early, and at that time unpublished, version consisting of a structured clinical interview using many interactive techniques such as questionnaires, card sorting exercises and self-ratings. It took about an hour to administer face-to-face and could be done by any member of the team. The problem drinkers’ group was facilitated by local unit staff. It was a psycho-educational programme with plenty of time for socialising and chat. Ironically, after one meeting I dropped into a pub on the way home and came across a couple of the members having a quiet pint.

My first automated version of an alcohol assessment tool was created at this time. The occasion was an open day held for the local community in the psychiatric unit. As a gimmick I wrote a simple programme in BBC BASIC (beginners all-purpose symbolic instruction code) for our psychology department’s BBC Acorn computer. This presented the questionnaires and card sort to members of the public who wished to have a go and assess their own drinking. It had novelty value if not great sophistication. This was the first example of a computerised interactive alcohol self-help program as far as I am aware. Later Hester and Miller (1989) published a report of their computerised behavioural treatment programme for a stand-alone PC and today, for the fee of \$34, they have a well-developed online version of the Drinkers’ Check-up

(<https://drinkerscheckup.com/>) and research reports on outcomes (Hester, Squires and Delaney, 2005).

#### Alcohol Services Pontefract and Wakefield (ASP&W)

The problem drinkers' service became well established and after a few years it was shortlisted for a Health Services Journal innovations award and two of us attended a presentation in London by the Minister of Health (Ken Clark). The publicity generated brought us to the attention of a local activist - Charles Elstone - who contacted me about a charity (ASP&W) he had started in 1986 offering free alcohol counselling to people from the local area. Charles had raised money with the support of the national charity Alcohol Concern and my role was to chair the committee and train volunteers in alcohol counselling.

Charles approached me with the idea of producing a self-help manual for problem drinkers. He had read "Let's Drink to Your Health" by Ian Robinson and Nick Heather (1986) in its original booklet form published by the Scottish Health Education council. This book presented cognitive behavioural techniques such as drinking diaries, goal setting and controlled drinking techniques for people to complete on their own. Charles thought we could produce a new version where the style of presentation was suited to drinkers from the business community. By this he meant smart graphics and diagrams, data presented as graphs (so they looked like a set of accounts) and a business style foolscap folder (see appendix 1 for examples). His idea was that it would look inconspicuous amongst personal papers at a business meeting. I believe that before retiring Charles had run his own company. Charles also coined the title "Down Your Drink."

The writing of DYD was a collaborative effort between Charles, a Health Educator called Toni Brisbee and myself. Charles provided some of the anecdotes, stylistic approach and narrative, Toni the graphics and layout and I contributed psychological knowledge. I was also responsible for designing and conducting an evaluation. Our motivation to produce the self-help manual was, I believe, implicit. As a local charity, with public money and



support provided by local and central government, we felt a commitment to provide help to a larger section of the community than was possible by just offering individual counselling. This was a social or public health ethos that resonated with the wider community approach that I was keen to develop.

In our evaluation we attempted recruitment via the media and placed adverts in the local newspaper. There was a freepost address and we informed readers that we would send them the manual in six weekly parts along with completed graphs of their alcohol consumption if they had filled in and returned their drinking diaries. Approximately fifty people responded to the adverts and packs were sent out, but unfortunately only four people agreed to be followed-up, so it was not possible to learn what they thought of the manual and why they did not respond (Linke, 1981). We did not have the resources to conduct further research with this group but were able to get feedback from a sample of university students (see chapter 4).

“Down Your Drink” then went into a second phase as a useful source of material for training, handouts for visitors to the service and an adjunct to one-to-one therapy for people with a drinking problem. In 1990 I left Pontefract and moved to a post in London (Islington). I brought a copy of DYD with me.

#### Islington Psychology Service, Friends and Family

This section describes the cross fertilisation of ideas and “synchronicity” that led to the development of the initial online version of DYD.

My new job was to coordinate a service for people referred for out-patient psychological therapy for a range of mental health problems. There was a well-developed alcohol treatment service in the borough, but this was for dependent drinkers, so usually our patients could not be referred. Coincidentally, sometime after arriving in London a non-work friend, who worked as a personnel officer for a different London borough, spoke to

me about a member of staff she was managing who had a drinking problem. Did I have any advice to offer? I sent her a copy of “Down Your Drink.” She was very pleased to receive it and reported later that the individual had made good use of the manual and reduced his consumption to the point that he could work normally. Buoyed by this I recommended it to a trainee clinical psychologist for use in a therapy case that I was supervising. The previous evening I’d had dinner with my brother who had told me about his new job in internet market research and development of online campaigns. It was the early nineteen-nineties and I’d had little idea of what he was talking about, so he had taken a while to explain it to me and it made an impression. During a supervision session with the trainee, when talking about the case, the ideas came together, and I had the thought that the six-week manual could be converted into an interactive format and delivered via the world wide web rather than by the post. Impulsively I went directly to the offices of our local research support network who were located on the same campus. I knew one of the staff a little and explained my idea to her and, naively, asked if she knew of any sources of funding. She immediately suggested that I discuss it with Professor Paul Wallace, but he had left the building for the day. At that point I was not aware that Paul had conducted both the first study of a brief alcohol intervention in primary care and the early studies in tele-health. I contacted Paul and he invited me to meet him in his office at the Royal Free Medical School and was immediately enthusiastic about the project and supported me in pursuing it. He has acted as a mentor ever since.

The prevalent model of clinical psychology that I had been trained in was that of the Scientist Practitioner. This meant understanding the findings from relevant research and applying them in practice. Conversely it also meant identifying unsolved problems and questions from clinical work and conducting research that might help improve practice. This was often actually difficult to do, but it was the ideal to be aimed for and there was a favourable attitude towards this type of activity in the psychology department in Islington. We were all allocated a nominal half day a week for continuing professional development and conducting research was a legitimate use of this time (although it was never enough and a lot of our own personal time and commitment was necessary as well). There was also structural support in the local NHS for research. A funding stream

depended on demonstrating research output in the form of publications. These were collated annually by the head of the service and the list was circulated among colleagues and senior management.

### The first Research Grants

I submitted a grant application with Paul's support to develop an interactive version of Down Your Drink to the Alcohol Education and Research Council (AERC)<sup>3</sup> and a second application to the North Central London Primary Care Research Network. Between 2000 and 2004 we received a total of £60,922 in research grants. I was the Principal Investigator and responsible for conducting the research, finance, dissemination and writing final reports for the grant giving bodies.

A condition of the grant set by the AERC took me in a new direction. They insisted that I discuss the content of the intervention with Professor Steve Rollnick. Professor Rollnick is one of the foremost authorities on Motivational Interviewing and an internationally renowned researcher and trainer. I went to see him in his office in Cardiff. He was keen that the programme should include the principles of Motivational Interviewing but was sceptical about whether Motivational Interviewing (MI) could be translated into a computerised format. He said that there had been some attempts to manualise MI and showed me a few printed examples; but he had doubts as the relationship was a crucial component in treatment and was left out of a manualised approach. The context of his comments was the then lively debate about the differences between Cognitive Behaviour Therapy (CBT) and MI approaches and the relative weight that should be given to the various exercises used in MI (such as the cost balance exercise) and the characteristic therapeutic stance ("acceptance" and "riding with resistance") of the MI therapist. The issue of the absence of a personal relationship with a therapist in computerised interventions is an important one that I return to later in this work. However, following the meeting I was left with the conviction that, even though there is no actual therapist in

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3 Now called Alcohol Research UK

the automated online programme I was envisaging, the writing style and tone could be one that resonates with the MI style and we should not adopt an overly technocratic procedural approach. The key elements to be conveyed in the narrative sections were to be non-confrontational, acceptance of ambivalence about change, collaboration, and a focus on building up the users' self-efficacy and adoption of an optimistic, but realistic attitude, towards change.

### Developing the site

To create the Website we needed to find a web designer and programmers. This required a procurement process that followed UCL rules. We created a specification and invited companies to bid for the work. An invitation was sent to my brother's company (Worldsites) as well as to several firms that were known to be involved in developing patient information websites. Three companies made presentations to the UCL panel – chaired by Paul Wallace – and Worldsites was awarded the contract. The part of the proposal that made them unique was the offer to engage the team in a market development exercise that was standard in Marketing. This was to be part of the website development process and it involved us answering a series of questions that helped to characterise the typical end user and define our USP (unique selling proposition). This approach was new to us and different from both the academic and medical/healthcare styles that we were used to and comfortable with. The information obtained provided a brief for the graphics, images and the design of the site.

The content was the same as the original printed "Down Your Drink" but rendered into an interactive format and illustrated by cartoons and photographs. These included the FAST screening questionnaire (Hodgson et al, 2002)<sup>4</sup> on-line quizzes, "mouse overs" revealing factual information, an interactive drinking diary, emailed "drinking tips" and a blood alcohol concentration calculator. There was also an associated email discussion group.

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4 A condition of the AERC grant was that we use this questionnaire as its development had been funded by them. We were given a pre-publication copy

Alternative versions of the “look and feel” were produced and shown to a group of potential users (recruited from a local sports centre) in a marketing workshop exercise. This group were asked to discuss their responses to the different versions and their comments were noted by the market researcher. There was no attempt by the researcher to be neutral or unbiased in the approach. Rather, the purpose was to find inspiration about how the materials could be imaginatively developed to attract “customers”. The product was not just a website but also a logo, leaflets and draft press releases to be used in a marketing campaign linked to a product “launch.” Examples of the finished product can be found in appendix 2, sample press releases in appendix 3 and a summary of the content in appendix 4 and public work 2. These were placed in health publications, GP magazines (such as Pulse), NHS Direct online and the web address was registered with popular search engines (principally Yahoo).

The site was launched in October 2001.

#### Developing the Questions and Building a Team.

The launch of the Down Your Drink pilot attracted interest and I accepted invitations to present our approach and findings at several scientific meetings. This provided opportunities to get constructive and sometimes critical feedback about the proposal. For example, at the launch itself (at the annual conference of the AERC), I was quizzed by Baroness Shreela Flather (the then chair) about the likely impact on equalities. At a meeting of the Division of Clinical Psychology Substance Misuse section I was asked whether the programme would replace face to face work and I was asked by GPs at the Royal Society of Medicine’s Telecare conference about barriers to implementation in primary care. All three of these themes would later emerge in the research programme that developed over the following fifteen or so years.

I wrote a research report for the AERC describing the work we had done (Linke, 2003) and later published our initial findings (Linke, et al 2004). It attracted considerable interest and was listed as the most cited article in *Alcohol and Alcoholism* that year. The project

was also shortlisted for an award by “NHS Innovations” and this provided some useful publicity for my employers as I was invited to attend the awards presentation dinner at The Globe Theatre in London and I invited the Chief Executive Officer of the Trust to attend as my guest. This undoubtedly helped to cement support for the project in my workplace.

Paul Wallace introduced me to Dr (now Professor) Elizabeth Murray following my presentation at the Society for Academic Primary Care’s London conference. Elizabeth was a leading researcher in eHealth and over lunch we had a lively conversation about whether it was possible to test an eHealth intervention in a randomised controlled trial. She raised potential methodological challenges and warned about the possible setback to the whole field if a trial was badly conducted or produced negative results. Elizabeth and Paul’s response to the discussion was, as I later learned, typical of both. They unflinchingly accepted the challenge. Within a few months Paul and Elizabeth invited me to join a research group at UCL to discuss the possibility of a trial.

The website had been left running following the initial pilot study and data automatically collected. It has been an important personal principle of the entire project that, as far as possible, the latest version of the site has remained available as a public service (it has always been publicly funded). With Elizabeth’s encouragement I set about analysing the data already collected and later published this as a cohort study (Linke, et al 2007).

In 2004 Professor Nick Heather invited me to present my plans and the initial data at the inaugural conference of INEBRIA (International Network on Brief Interventions for Alcohol Problems) in Barcelona. During the telephone call in which he invited me he mentioned that he hoped that at the conference I would meet an up and coming young researcher, Dr (now Professor) Jim McCambridge. He felt that we would have common interests. Nick’s intuition was correct. Following the conference we had time to take a walk around the city and we ended up in a bar on the beach engrossed in conversation about whether and how psychological therapies could be transferred into a web-based environment. On

the strength of this conversation and mutual interest I invited Jim to join our group when planning the trial.

### Designing and Implementing the trial

Paul created a research team to prepare a bid to the National Prevention Research Initiative (NPRI) managed by the Medical Research Council (MRC). We designed a trial to compare DYD with a control condition following the MRC's complex intervention model (Craig et al, 2008). It was a phase 2/phase 3 trial with stop go criteria between the phases which were overseen by a trial management committee made up of members of the public, representatives from the MRC and the NPRI and chaired by Professor Colin Drummond.<sup>5</sup> I attended these meetings as an observer. My specific responsibilities in the trial were to redevelop the website (see appendix 5 for the new look home page) and contribute a psychological perspective to the methodology. This was my introduction to the full paraphernalia of a large randomised controlled trial. Our procedures for data management, confidentiality, randomisation, blinding etc. were all closely scrutinised along with our application to the ethics committee, Patient and Public Involvement (PPI), choice of primary and secondary outcomes, statistical analysis plan, deliverability of the research and finance.

During the development phase unexpected complexities arose. Down Your Drink was endorsed by Alcohol Concern and they now wanted to move the hosting of the website from Worldsites to their own server. This required a legal document to transfer the Intellectual Property Rights (IPR). There was no-one on the team who had the skills to achieve this and the ownership of the IPR was unclear. There were different elements: the idea itself, the code, the images and the intellectual content. Defining the IPR remains a problem to this day, but we managed to resolve the transfer with some good will and a simple letter. We put a copyright statement on the site to identify the authors in the "about us" section.

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<sup>5</sup> Professor of Addiction Psychiatry and Consultant Psychiatrist at the National Addiction Centre, Institute of Psychiatry, Psychology & Neuroscience, King's College London.

The website designer and programmer (Richard McGregor) was key to the whole project (and he has remained so in all the various iterations of Down Your Drink). Richard had a contract with Alcohol Concern to provide their website. It was fortunate for us that he had the intellectual grasp, technical expertise, creativity and enthusiasm to build the websites and tools that we required. At a later stage Alcohol Concern decided that they were no longer able to host “Down Your Drink” on their servers so, after some more documents, Richard took over the hosting as well and his company – Codeface – provided all the technical support for what had become a very complex enterprise.

Designing a pragmatic trial and conducting it entirely on line presented numerous challenges. For example:

- Recruitment. Would this be sufficient to detect a difference if one existed (we had based our power calculations on the earlier cohort study)? We did not know how successful the recruitment strategy would be as there were no previous online research studies to estimate this from.
- Was there an ethical basis for using financial incentives to reduce attrition and how could we clearly distinguish between retention to the study (i.e. providing data) and retention to the intervention?
- High levels of drop out were expected, so was there a theoretical or empirical basis on which we could define a minimum “dose” of the intervention. In other words, do we include only those that had used the site a certain number of times or completed key exercises (such as the drinking diary)? Or do we include everyone who had been exposed to the website?
- Should the analysis plan be “per-protocol” or “Intention to Treat”? Per-protocol analysis is a comparison of treatment groups that includes only those patients who completed the treatment. Intention-to-treat analysis is a comparison of the treatment groups that includes all randomised patients and missing data is allowed for.<sup>6</sup>

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<sup>6</sup> We made the unusual choice of pre-specifying that the primary analysis would be “per protocol” but we also conducted a secondary “intention to treat” analysis imputing missing values.



- Could we design the websites to deliver both the intervention and collect data?
- What should be the branding (NHS, UCL or a new one that was unique to the study)?
- Do the research instruments (questionnaires) behave online in the same way as they do off line (we chose to conduct a parallel reliability study on our primary outcome measure to test this)?
- What would constitute an adequate comparator?
- How do we manage the response burden with so many measures?

The results of the study and interpretation are discussed in detail in chapter four. The trial was a scientific success in the sense that we had conducted it entirely on line and achieved the level of internal validity that we had hoped for. The main finding was of no difference between the two conditions. We discussed at length what this meant. There were two narratives to be incorporated. It could be argued that the trial was a failure in that there was no advantage for the intervention. It could also be argued that the trial demonstrated a widespread and potentially sustainable demand for Internet based interventions for people with hazardous alcohol consumption.

### Dissemination

In this section I describe some of the different settings where Down Your Drink was introduced to provide an alcohol reduction intervention.

The references to “we” in this section are to various members of the original team that undertook the main trial along with other colleagues from the eHealth unit who helped. Other collaborators are also included as team working and organisational cooperation are essential for successful deployment in real world settings.

Shortly after the completion of the trial I was contacted by Iona Lidington, Associate Director for Public Health in Kingston Primary Care Trust (PCT), with a request to create a version of “Down Your Drink” to be used in her locality. She arranged for the local PCT to pay for their own copy to which they added their logo and information about local

services. We developed a service model, based in GP surgeries, where an alcohol worker supported patients in using the intervention (Murray et al, 2012). The project required alignment with the performance measures used by the PCT and the collection of data via the GP record systems so that GPs could be paid (and hence incentivised) for providing this “enhanced” service.

This was possibly the first attempt to formally integrate an online intervention into an existing care pathway. Planning required multiple trips to the PCT headquarters and seemingly endless meetings. Elizabeth and I drew heavily on our experience as practitioners with knowledge of primary care to enable the project to get started and problem solve the large number of practical hurdles we needed to overcome. We also had to provide training and support to our worker who was recruited and employed by the PCT (not us) and who we could see face-to-face only infrequently.

Don Shenker, the former Chief Executive Officer of Alcohol Concern, took a great interest in our project and the potential for digital interventions in the workplace. Don set up the Alcohol Health Network (<http://www.alcoholhealthnetwork.org.uk>) in 2012 – a community interest company – to consult to and work alongside employers. Don invited me, Paul Wallace and others to join the advisory board and our role was to provide clinical, strategic and academic advice. This necessitated discussions on how his projects could be rigorously evaluated and on how the available evidence should be interpreted. Don used “Down Your Drink” as the original model for his work and then evolved his own set of bespoke online tools for different projects. He openly shared his projects, knowledge and data with us and contributed in this way to the growing body of experience of how online tools might be used in practice. The collaboration with Don and Paul has continued in several ways. Don straddles the commercial sector, public sector, third sector and academic worlds and we are both members of the London Alcohol Misuse Prevention (LAMP) group (chaired by Paul Wallace), which promotes online Brief Advice on Alcohol for the Safe Sensible London Partnership. He is also part of the South London Health Innovation Network (HIN) which adopted brief interventions as a specific

focus. These settings provide opportunities to develop and refine strategic ideas about how online interventions can be deployed.

The opportunity to conduct a formal evaluation of an online intervention in an occupational setting was the Health on the Web study (Murray et al, 2013). Through a mixture of personal and institutional contacts we were able to work with a large, international technology company to provide an alcohol screening embedded within an online health check. “Down Your Drink” was included for members of staff who wished to use it. Although the company were keen to involve us it was also clear that we were required to fit in with their expectations of timings, content and management culture – an interface of cultures that it is crucial to understand in implementation (see further discussion in reflections section below).

#### Redevelopment.

The version of Down Your Drink used in the workplace projects was the one I had developed for the research trial (Linke et al, 2008). I remained happy with the content and design, but a few technical difficulties emerged and it was looking a bit tired and old fashioned and needed an upgrade. The importance of these hidden costs and the budgetary planning required to ensure the maintenance and updating of a website was an issue we had identified in our “Elephant in the Room” paper (McCambridge et al, 2010). The actual IT costs of running the Down Your Drink trial had turned out to be twice the amount originally estimated.

The background research to update the appearance was taken on by MSc students from UCL. They undertook a “think aloud” study working with a group of hazardous/harmful drinkers (identified by a score of 8 or more on the Alcohol Use Disorders Identification Test). The volunteers were asked to use the intervention and to say out loud whatever was in their minds as they did so. The students used this approach to explore the acceptability of Down Your Drink in a workplace setting and based on the results redesigned the look and feel of the site by changing colours, images and designs etc.

(Renouf, S, 2013). See appendix 6 for the homepage of the current freely accessible version of the site.

### Current research directions

One attraction of online interventions is that they can be made readily available in a diverse range of settings. A critical question, however, is whether they are as acceptable and effective as the traditional face to face version (non-inferiority). There are practical barriers to be addressed in answering these questions; we designed a feasibility study to explore them. The DIAMOND study (Digital Alcohol Management on Demand) was adopted by the North Thames CLARHC (Collaboration for Leadership in Applied Research and Care) and a video describing the project can be found on their website.<sup>7</sup>

In the video I described how I had redesigned Down Your Drink to more closely resemble a typical course of alcohol counselling. This required restructuring the package into six consecutive parts as this more closely matches usual treatment. This decision was also supported by my impression that attrition from the intervention appeared to be lower in the original six-week version of Down Your Drink (DYD<sub>1</sub>) than it had been in the trial version (DYD<sub>2</sub>).<sup>8</sup> I was also aware of a successful study of online treatment of cannabis users that had used a six-week model (Rooke et al, 2013) and it seemed reasonable to read across from this into the alcohol field.

The new version was renamed HeLP-Alcohol (Healthy Living for People who drink Alcohol) (see Appendix 7 for the Homepage and example). The content was the same as DYD, but it was reprogrammed so that the user had to complete a pre-specified number of sections in a module before they could go on to the next. The choices of sections were based on my clinical view about which components and interactive exercises were most likely to be

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<sup>7</sup> [https://clahrc-norththames.nihr.ac.uk/behaviour\\_and\\_engagement\\_with\\_care\\_theme/diamond-digital-alcohol-management-on-demand/](https://clahrc-norththames.nihr.ac.uk/behaviour_and_engagement_with_care_theme/diamond-digital-alcohol-management-on-demand/).

<sup>8</sup> I did not look closely at the data

effective in promoting change (based on CBT<sup>9</sup> and MI<sup>10</sup> principals). Examples are the self-assessment tools, drinking diary, normative feedback and the decision balance matrix. There was also an attempt to introduce aspects of “gamification” (in this case “levels”) to promote adherence to the intervention. I developed anonymised case histories presented as stories split into a series of episodes so that the user had to complete one section before gaining access to the next one (and finding out what happened – like a “soap opera”). I also developed outline scripts for the case histories and engaged a theatre company<sup>11</sup> to develop them into short films, which were then embedded into the website alongside the written stories. The basic design of the public version of DYD was retained, but with a new logo and branding to match the “stable” of other online behaviour change interventions developed by the eHealth unit at UCL. I further developed the content of HeLP-Alcohol (including the case studies) and published a self-help book (“Thinking About Drinking”, Linke 2012) for the general reader.

Implementation of the DIAMOND study required a varied skill set and a large team. The study was designed to be conducted in community alcohol treatment projects (Hamilton, 2017). We needed expertise in public health and commissioning to identify the community services and engage the projects’ managers, we needed experienced research management skills for implementation and professional and clinical experience of treatment settings. As with the Kingston study the “lived experience” of team members (2 GPs, 1 hospital doctor and myself) contributed enormously to the development of our approach to recruitment and implementation. Furthermore, my awareness of the practicalities of research being conducted elsewhere in community settings provided ideas and insights about how to overcome barriers. One specific example was that through my membership of the LAMP I’d had the opportunity to discuss with Professor Colin Drummond his team’s experience of recruiting in a hospital setting for the SIPS trials

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9 Cognitive Behaviour Therapy (CBT) is a psychological treatment method based on the principals of cognitive and behavioural theory. It focusses primarily on helping a client resolve current problems using techniques to change behaviour and beliefs and is widely used to treat alcohol problems (see chapter 2 below)

10 Motivational Interviewing (MI) is a psychological treatment approach to substance misuse that helps clients become aware of ambivalence about change and resolve it. MI was developed from the work of humanistic psychologists such as Carl Rogers (see chapter 2 below).

11 Chickenshed Theatre Company

(Drummond, 2014) and their use of a research assistant based in the clinic setting to encourage recruitment.

Another new direction is the EFAR <sup>12</sup> primary care studies conducted by Paul Wallace's research group in Italy (Struzzo P, Scafato E, McGregor R, et al, 2013) and Spain (López-Pelayo H, Wallace P, Segura L, *et al*, 2004), Australia and the UK. I have not personally been involved in this research stream but have kept abreast of developments as I was consulted on the adaptations made to the websites and had to agree changes to the content. They have translated Down Your Drink into Italian and Spanish having first subjected it to further user testing and renamed it as "Healthier Drinking Choices" with a new design and look (see appendix 8). The innovation in this research is the way it is delivered. GPs facilitate access to the website by giving patients a leaflet with personalised log in details. Once registered the patient is shown a photo of their doctor with a personalised message introducing the intervention and encouraging their participation. Results suggest a good success rate in converting risky drinkers into website users (Wallace, 2014). This "download your doctor" approach seems to have potential for bridging the gap between a fully automated public website and a more personal approach which is often sought by patients. It has some similarities with "blended" interventions used in online learning and psychological treatments (see, for example, Erbe, Eichert, Riper, and Ebert, 2017).

In my current project I have adapted some elements of the EFAR approach for a secondary care mental health setting (see appendix 9 for the Home Page). Patients are selected by mental health professionals and given a log-in that automatically directs them to the section of the site that matches their primary diagnosis. So, for example, those with anxiety will encounter information specific to anxiety, those with psychosis will be given information about psychosis etc. Along the pathway they see a video introduction and welcome by the Medical Director as well as videos by topic experts. Following the specific topic information they have access to the normal Drinking Choices website (with local NHS branding). The information patients enter onto the site is not viewed by their

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<sup>12</sup> Effectiveness of Facilitated access to Alcohol Reduction websites

mental health practitioner, but they are encouraged to voluntarily share the information with the practitioner if they wish. The practitioner is, however, able to see their patient's website use (number of visits, pages visited, time in each session etc.). This project is currently at the development, feasibility and acceptability testing stage and will be subjected to an audit.

### Theoretical Analysis of Implementation

In this section I consider theoretical perspectives on the policies and contexts that shaped DYD. This enables a more critical and less personal view of its development.

A dominant view of decision makers in the NHS (and much of the public sector) is that interventions should be evidenced based. In medical settings, within the United Kingdom, this usually means that they are endorsed by the National Institute for Health and Care Excellence (NICE). Administrations in other countries have similar bodies. The development of the research programme that underpins DYD reflects this as it led us to collect "gold standard" evidence in a Randomised Controlled Trial (RCT) that could inform policy. Alongside "Evidence Based Practice" sits "Practice Based Evidence". This utilises data collected in routine settings to guide and improve practice. This approach has been adopted widely in mental health services, particularly in psychological therapies (see, for example, Lucock et al, 2003). The DYD implementation studies sit within this tradition. More broadly "Practice Based Evidence" is part of "Implementation Science" which seeks to explore and guide how interventions can be sustainably introduced into routine service delivery. Aarons, Hurlburt and Horwitz (2011), for example, take a schematic approach to describing the influential variables they identified. They list internal factors such as service and organisational settings, readiness for change and the degree of consumer support and advocacy; external factors such as sources of funding, contracting arrangements, public policies and academic endorsements; and characteristics intrinsic to the intervention itself such as how good a fit the innovation is to the problem that it is designed to solve and the leadership qualities of the developers. Factors such as these

interact in complex ways and will influence how, and whether, DYD, and online interventions in general, become integrated into health care pathways.

### The Production of Knowledge

Policy implementation is not a straightforward translation of evidence into practice. The development of DYD exemplifies the complex interactions between evidence from trials and practice, expert experience (both user and professional), policy, funding opportunities, service development and leadership. These interacting factors produce knowledge about this specific intervention and, by extension, other online behaviour change interventions, and how users behave in an online environment. Freeman and Sturdy (2014) provide a conceptualisation of the different forms knowledge in public service settings can take. They encourage a broad view of what constitutes knowledge. They list information, ideas, arguments and well tested beliefs that encompass both professional and academic knowledge. In their book Freeman and Sturdy provide a wealth of examples from different countries of how knowledge can drive, shape or inhibit policy implementation. They note that “policy makers have an ideological preference for clinical trials” (page 3) and their model is an antidote to that. They describe knowledge as embodied, inscribed and enacted.<sup>13</sup>

Embodied knowledge is held by individuals and employed or expressed by them as they go about their activities. It includes tacit knowledge that is not expressed in verbal form.

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13 This broad approach also shares features of some contemporary psychological, philosophical and neuroscientific accounts. For example, Iain McGilchrist (2009), who is both a psychiatrist and a literary scholar, discusses the cognitive and brain science views of the different ways in which we come to know the world. His primary argument is that different types of knowing are located within different hemispheres of the brain and give rise to different modes of perception. Neither on its own is sufficient for a rounded view and the growing dominance of the analytical and narrow focus of the left hemisphere, and the corresponding diminution of the broader right hemisphere, is leading to an increasingly technocratic society. The right hemisphere is also more closely associated with the body and McGilchrist gives examples of right hemisphere knowing that appears to overlap with Freeman and Sturdy’s conceptualisation of embodied knowledge. He also says that knowledge begins with the body and then moves to the formal linguistic faculty of the left hemisphere (inscription perhaps) and then returns to the right hemisphere where it has a role in shaping the culture in which we live our lives (enacted knowledge). It is not necessary to accept his bilateralism hypothesis wholesale to see that knowledge is dynamic and not wholly cognitive.



This may be a skill such as riding a bike or how to use a keyboard. It includes “know how” and procedural rules such as how to read situations or respond to them.

Inscribed knowledge includes artefacts, texts, pictures and diagrams that are incorporated into tools and machines. In policy making they are manifestos, white papers and executive summaries. This knowledge is characterised by being written down in a stable format such as in a record. This propositional knowledge that can travel across time and distance (such as in emails). Inscribing knowledge augments embodiment – that is particular ways of seeing, thinking and knowing – so that it can be shared with others. Inscribed knowledge is the traditional tool of policy making.

Enacted knowledge is the mechanism by which embodied and inscribed knowledge acquires meaning and significance. When brought together they lead to action and whilst different from embodied and inscribed knowledge, enacted knowledge can add to them. Enacted knowledge exists in the public sphere and so, through observation and public scrutiny, it changes and develops.

The value of Freeman and Sturdy’s approach to policy development can best be seen in the practical examples described in their book, which are taken largely from education and mental health policy. For example, Thunus, Cerfontaine and Schoenaers (in chapter 10) studied a project to organise mental health care networks in Belgium. Practitioners worked closely with local pilot schemes before the main projects were set up. They set out the issues they identified from working explicitly with knowledge using the framework:

1. The embodied knowledge gained from engaging with practitioners in real settings added to the appreciation of the problems encountered when attempting to enact and inscribe the knowledge in a way that would appeal to, and therefore influence, policy makers.

2. Circulating inscriptions around the policy makers helped to describe and direct local action. When this wasn't done it failed to successfully involve local policy makers.
3. The embodied knowledge of the actors in their roles, professions and affiliations interfered with enactment. They had their own preferred ways of knowing that were not easily absorbed into the new model.
4. There was a need to understand how the knowledge and interests of the actors is constrained by their location within social networks and of power politics.

### Reflections on the use of knowledge in developing Down Your Drink

In the following section I reflect on the history of DYD to see how different types of knowledge have worked together to form the "product" that it has become. I examine how the different categories of knowledge have had an impact and, in so doing, implicitly critique the notion that the choices and direction are solely set by scientific data and evidenced based policy.

I can see numerous occasions where embodied knowledge played a role. This is knowledge that was implicit and taken for granted and would not be given prominence without a conceptual framework such as that which Freeman and Sturdy provided. I will give two examples:

1. Translation of treatment models into the online format.

Clinical experience gained from working with a range of clients who drink hazardously enabled me to have a strong sense of how to select which treatment techniques to include, how to frame them and pace their delivery, the tone of language to adopt etc. My early career experiences of talking "naturally" with heavy drinkers in the Pontefract problem drinkers group bore fruit. When developing each version of the intervention I "instinctively" knew what to include and what to emphasise. At that point there was little

in the literature to provide guidance and indeed the topic was actively debated and researched.<sup>14</sup>

Another way to describe this type of knowledge is the four stages model (attributed to Gordon Training International and its employee Noel Burch in the 1970s) and this has been adapted to many settings, for example, to describe different levels (or stages) of therapist competence (Mindtools<sup>15</sup>). An experienced therapist would expect to be “unconsciously competent” where there is a high degree of implicit or tacit knowledge without them being aware of it. The risk, though, is that without continuing professional development and training the standards can slip so it is important to keep evaluating the level of skill.

The validity of the choices I had made was later borne out when researchers from the Institute for Behaviour Change at UCL published a taxonomy of empirically validated Behaviour Change techniques (BCTs) (Michie, van Stralen and West, 2011) and went on to identify the key techniques in alcohol interventions (Michie, Whittington, Hamoudi et al 2012). They identified that self-monitoring was considered a key feature of successful interventions and the “drinking diary” (a self-monitoring tool) was the primary interactive feature in DYD and included in all versions of the site.

The recently published Cochrane Review of online alcohol interventions tentatively concluded that the BCTs of behaviour substitution, problem-solving and credible source were associated with effectiveness (Kaner, Beyer, Garnett et al, 2017). The learning point is that the only one of these that we gave much attention to was “Credible Source” and specifically we included the NHS logo in the home page of all versions of the intervention and emphasised the UCL branding in the research (data collection) website in the RCT. Future iterations of alcohol online websites will need to include, and give a greater emphasis, to the missing BCTs.

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14 See discussion of “Project MATCH” in section below.

15 Mindtools “The Conscious Competence Ladder: Keeping Going When Learning Gets Tough” [https://www.mindtools.com/pages/article/newISS\\_96.htm](https://www.mindtools.com/pages/article/newISS_96.htm). Published by Mindtools Ltd. London (Accessed November 04, 2017)

There may be a tension between the embodied knowledge of the experienced practitioner (in this case me) and the scientific evidence derived from scientific studies. The goal is for these different types of knowledge to be in a Quality Improvement (QI) cycle to enhance the effectiveness of an intervention. This is very similar to the version of the “scientific practitioner” model in which I was trained. One aspect is the critical analysis and absorption of the research evidence and another is the curiosity and systematic approach to finding answers to questions that produces “embodied” knowledge through experiential learning which then shapes how we act and apply our professional skills.

## 2. Incorporating the intervention in naturalistic settings

The practical aspect of conducting the implementation studies required careful negotiation with service providers and an understanding of the systems and care pathways in which they worked. The clearest example of this was the Kingston study. We had to be credible to senior staff in the public health department, commissioners, General Practitioners (GPs) and Health Centre staff (receptionists and nurses); as well as having to select, train and supervise our researcher in how to conduct interviews, manage potentially difficult situations (face to face and on the telephone), tactfully negotiate office space and interact with colleagues who had different roles and priorities. To achieve this, we (Elizabeth Murray and myself) had to make use of a range of skills, habits, attitudes, non-verbal communication styles and tacit knowledge of primary care. Furthermore, we needed to understand how templates for recording information could be added into the various systems of electronic patient records and the detail of how the financial reimbursements for GPs conducting alcohol assessments worked.

The crucial component was the knowledge of how to persuade busy, and often skeptical, GPs that it was worth their while investing effort into the enterprise and how to overcome the barriers they were likely to face. The (limited) success we had was because we were able to show them (by the way we spoke and anticipated their questions) that we had done it ourselves. One example demonstrates this. We understood from our

experience of talking to colleagues – both informally and in a focus group (Linke, Wallace and Harrison, 2005) - that GPs might not want to screen for hazardous drinking because if the patient scored positive they would have nothing to offer the patient by way of treatment and this would be an additional burden on them. We explained that in this type of situation the website itself was a reasonable thing to offer and they accepted this as a solution.

The practical thread of creating and implementing the websites was accompanied by a sustained effort to add to the sum of Inscribed knowledge about online alcohol interventions. The primary activity was reading and comprehending the growing published literature on alcohol treatment, and screening and brief interventions (SBIs), and then publishing papers that reported on our work. These papers form the spine of this thesis, which, it is hoped, is an addition to inscribed knowledge. It is by the publications of guidance, papers and systematic reviews that the methods employed, the behaviour of the users and outcomes are preserved and conveyed to the community.

The activity of publishing research significantly shaped the direction of the project overall. It is unlikely that DYD would have been funded by public bodies to the extent that it was without undertaking a research trial of sufficient quality to be published in a highly regarded (high impact) journal. Once published our work influenced the ongoing development of both our own work and that of others in the field. The data we reported, and the descriptions of our methods, enabled the research activity to be understood by others sufficiently for it to be included in the systematic review that formed the basis of the conclusions in the Cochrane review and its recommendations.

The development and the implementation phases of the online websites are example of how different types of activity and understanding interacted to create enacted knowledge. I give two illustrations of this:

1. The content of all the versions of the website consisted of written informational content to be read, interactive pages to help the user actively engage with the materials and practical online tools to be used in actual drinking or risky situations

(inscribed knowledge). Experience of using treatment manuals and engaging in therapy with problem drinkers had provided me with a fund of case studies and personal experience of overcoming treatment barriers, anticipating the kinds of difficulties people experience when changing their drinking and the style of verbal interaction that can be helpful etc. This “embodied” knowledge shaped the “enactment” - the tone and pacing of the writing and the images chosen to illustrate the content and the sympathetic non-judgemental style of presentation.

The feedback we received from the various versions of the site influenced later developments. The comments from users providing written responses to the interactive exercises suggested that the tone we had chosen fitted the target groups identified in the market research exercises, but the feedback from the students in the “thinking aloud” exercise led us to redesign the home page and improve the functionality.

2. The introduction of DYD into health care and corporate environments posed a different kind of challenge. We needed to be able to provide written and verbal summaries of the evidence base; but both settings also had highly elaborated policy frameworks (inscribed knowledge) such as contracts and information governance in health settings and employee and occupational health policies in the corporate setting. We needed to demonstrate procedural knowledge and professional standards in our interactions with the key decision makers to inspire confidence and gain support from them. Bringing these two types of knowledge together in meetings enabled the successful implementation of the studies.

There is a question about whether awareness of the Freeman and Sturdy model would have improved the DYD project overall. It is difficult to know. The importance of inscribed knowledge was overt and directed us towards key decisions such as applying for research grants and writing research reports; whereas the embodied knowledge was not explicitly recognised. It is difficult to see how we would have been awarded the grant money without aligning ourselves with the dominant narrative of evidence-based

practice. The alternative would have been to obtain sponsorship from charities or the alcohol industry. Charities could probably not have provided sufficient funds and I perceived a potential conflict of interest in obtaining money from the alcohol industry so did not pursue this.<sup>16</sup> The team that I led were all senior experienced professionals who “embodied” the practical know-how to get the project completed and we took this knowledge for granted.

It was possibly embodied knowledge that helped form the motivation to be involved in this type of work in the first place – the desire to make evidence-based alcohol interventions more available. Through our direct contact with patients we had all seen (and felt) the need for online brief interventions and treatments and we shared a public health orientation to health care. This enabled us to work together as a team and our experience and track records convinced the reviewers of our grant applications that we had the capability to achieve the objectives we had set out. If we had not, collectively, had this experience, I doubt we would have undertaken the project at all.

Perhaps the advantage of theoretical and conceptual models is that, if used, they can describe what was achieved in a way that others could follow. The practical aspects of development and implementation were not described in the journal articles, so are not available for others to see what we did. This is a lack of transparency as it implies that the development was a smooth process based only on data and scientific conclusions. The story described in this contextual statement makes it clear that many other factors were at work. The exception to this lack of transparency about the process is the “Elephant in the Room” paper (McCambridge *et al.* 2010) which shows some of the pitfalls we encountered. An example of the value of this comes from an experience in my NHS job. I have instituted and led a clinical digital development group. One member of the group is creating an online practice development tool for nurses at Middlesex University. I shared the “elephant” paper with her and she told me that this had been valuable in helping her plan and implement the website she was deigning for the project.

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16 I was approached by Drinkaware at one point to be a consultant/advisor to their Website but I declined.

The importance of planning for implementation is increasingly recognised by research councils and academic bodies who manage funds. In some cases it is their primary role (such as the CLARHC) and in others the funders require clear evidence of planning for implementation in the application process (e.g. The translational research stream of the MRCs strategic plan, 2016). The introduction of explicit models of knowledge can help with this. There are also other candidates. The schematic approach of Aarons et al (2011) describes the multiple factors that influence the trajectory of implementation. Within the eHealth realm the process whereby new information technology-based applications become (or fail to become) incorporated into healthcare systems is being studied using a sociological “normalisation process theory” and implementation is supported by an e-health implementation tool kit (MacFarlane, Clerkin, Murray et al, 2011). Finally, the approach adopted by human factors researchers and software developers is entirely different (which I discuss in chapter two) and relies heavily on enacted knowledge and public feedback.



In this literature review I set out the scientific and research context for the work. Inevitably, during the long period of my research the literature had grown and evolved, and I have had, therefore, to be selective in what I have chosen to include. There have been different waves of activity which reflect changing interests and concerns and I have tried to reflect these in my account.

A peculiar facet of this review is that the publication of papers about DYD has had an impact on the research literature itself. For example, the paper presenting data from the original pilot study (Linke et al, 2004) was the most downloaded paper from the journal in that year and has often been cited by others working later in the field. Therefore, the papers I include in this review are not the same ones that I relied on when first starting out. And the articles in the final part of this chapter discuss current and future directions which may be, in part, influenced by my research, but DYD has not been part of them.

### Definitions

Definitions in research serve different purposes. It is important to have explicit, public and agreed terms to facilitate communication between colleagues and also between researchers and the public, clinicians and policy makers etc. Definitions also partially define the field and may reflect considerations of wider concern. For example, in a recent project I searched for guidance suitable for older drinkers. I sent a request to an email group of researchers asking for information about *safe* drinking guidelines and received a swift and terse reply from an eminent researcher stating that there were no *safe* levels of consumption as alcohol is carcinogenic and I should only refer to increased or decreased levels of harm.

Another example is that of *binge drinking*. Herring et al (2008) contrasted the use of operational definitions of *heavy episodic drinking*, descriptions that referred to the social

and individual effects associated with *binging*, and the need for a broader range of categories to include a range of drinking behaviours suitable for epidemiological research, clinical treatment and advice for public health purposes. Furthermore, there are now possibilities of going beyond self-report to physiological measures and real time psychological data collected automatically by mobile technology (Ceballos and Babor, 2017). Advances in *mhealth*<sup>17</sup> and ubiquitous computing will no doubt accelerate this trend.

The definitions given below are not comprehensive and relate primarily to those that have direct relevance to the background to “Down Your Drink.” Where possible I have made the source of the definitions clear.

The World Health Organization distinguishes between *hazardous* drinking, a pattern of alcohol consumption that increases the risk of harmful consequences for the user or others; *harmful* drinking, which refers to alcohol consumption that results in harms to physical and mental health or detrimental social consequences; and *alcohol dependence*, which is a cluster of behavioral, cognitive, and physiological phenomena that may develop after repeated alcohol use (Fleischmann, Fuhr, Poznyak, & Rekve, 2011).

*Alcohol-use disorders* are medical terms used in published guidance, such as that produced by National Institute for Health and Care Excellence (NICE, 2011), describing problem drinking that includes both “alcohol dependence” and “alcohol abuse.” These may be mild, moderate, or severe.

*Alcohol-related risks* and *alcohol-related harms* refer to the direct effects of alcohol on the body, increased risk of accidents, violence, antisocial behaviour, risky behaviours, increased personal vulnerability, and negative impacts on families, occupation and education.

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<sup>17</sup> Mobile health

Alcohol consumption is measured in *standard drinks* or *standard units*. The definitions of these terms vary between countries and are converted to grams of pure ethanol to aid comparison. In the United States, a standard drink contains about 14 grams of alcohol; in the United Kingdom, a standard unit contains 8 grams; whereas in Ireland and Australia, it is 10 grams and 18 grams. Charts have been developed to help drinkers calculate their consumption by providing local specific information about how much alcohol is contained in a normal serving or a standard glass. For example, in the United Kingdom, a large glass of standard-strength wine contains 3 units, and a small glass contains 1.5 units. These amounts are not the same in each country and change over time. To continue with the U.K. example, pubs will often sell 250 ml glasses of wine as standard; whereas in the past, 125ml glasses were more common.

#### *Heavy episodic drinking or binge drinking*

The Office for National Statistics (2017) defined binge drinking as males who exceeded 8 units of alcohol on their heaviest drinking day, and females who exceeded 6 units on their heaviest drinking day. In the United States the National Institute on Alcohol Misuse and Alcoholism (2017) define heavy episodic drinking as a pattern of drinking that brings blood alcohol concentration (BAC) levels to 0.08 g/dL. Binge drinking is one of the most important indicators for acute consequences of alcohol use, such as accidents and injuries.

As there is no consensus that any amount of alcohol consumption is safe, the terms *risk* or *harm reduction* are preferred. Guidance on risk reduction is often produced by public bodies and revised as new evidence emerges. The U.K. Chief Medical Officer's current guidance states, for example, that both men and women should not regularly drink more than 14 units per week. If 14 units per week are consumed, it is best to spread them evenly over three days or more, because heavy drinking sessions increase the risks of death from long-term illnesses, accidents, and injuries (Chief Medical Officer, 2015).

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18 Global Health Observatory data repository (accessed on 03/04/18 from <http://apps.who.int/gho/data/view.main.54180>)

## Consumption

The measurement of alcohol consumption relies on self-assessment because it is rarely possible to obtain objective physiological measures such as blood alcohol levels. Self-reports and surveys are frequently employed; however, these may be subject to error through memory or response biases. Data obtained in this way significantly underestimate the amounts consumed compared to that which would be predicted by alcohol sales. For example, in a report for the UK charity *Alcohol Concern*, Bellis, Hughes, Cook and Morleo (2009) found a discrepancy between alcohol surveys calculating consumption and actual alcohol sales that equalled 430 million units a week. This is the equivalent of a bottle of wine per adult drinker per week unaccounted for.

In research studies frequency and quantity measures are obtained through structured drinking diaries such as the alcohol Timeline Follow Back (TLFB). This uses a calendar of dates and events to prompt recall to better enable retrospective estimates of daily drinking over a specified time-period. The TLFB has been shown to have good psychometric characteristics with a variety of drinker groups (Sobell & Sobell, 1992).

The United Kingdom's General Household Survey (GHS) includes questions about drinking in its questionnaires. It asks about the maximum daily amount drunk in the previous seven days and how much they consumed on their heaviest day. Average weekly consumption is calculated by asking people how often and how much they have drunk over the previous year and estimating from that.

Estimates of Alcohol Consumption in different regions.

On average, every person in the world aged 15 years or older drinks 6.2 liters of pure alcohol per year (recorded consumption). But less than half the population (38.3%) actually drinks alcohol, so this means that those who do drink consume on average 17 liters of pure alcohol annually (World Health Organization, 2014).

The World Health Organisation (2014) reported that the region with the greatest number of alcohol-use disorders was Eastern Europe and prevalence in the Russian Federation was 16.29%. Western European rates typically ranged between 4.5% (France and Germany) and 6.4% (United Kingdom). There was considerable variability between American countries (5%–10%). The United States prevalence was 5.5%; whereas Colombia was 10.3%. However, a recent study using an updated definition of an alcohol-use disorder found the 12-month and lifetime prevalence of alcohol-use disorders in the United States to be 13.9% and 29.1%, respectively (Grant et al., 2015).

The regions with lowest prevalence of alcohol-use disorders are Southeast Asia (mostly less than 3%) and Africa (0.5%–1.5%), with Thailand (10.2%), China (7%), and South Africa (3.64%) being exceptions (World Health Organization, 2014).

In the United States, 25% of those aged 18 or older reported that they had engaged in binge drinking in the past month (Substance Abuse and Mental Health Services Administration, 2014). In Great Britain, 12.9 million drank more than 4.67 units on their heaviest drinking day, and of these, 2.5 million (9%) drank more units on their heaviest drinking day than the weekly recommended amount of 14 units (Office for National Statistics, 2016).

It is apparent from this data that in the UK and worldwide there is a significant level of heavy and risky drinking. The charity Alcohol Concern has summarized the impact of this consumption.<sup>19</sup> In the UK, in 2015, there were 8,758 alcohol-related deaths (around 14 per 100,000 people). The mortality rates are highest among people aged 55-64. Alcohol misuse is the biggest risk factor for death, ill-health and disability among 15-49-year-olds in the UK, and the fifth biggest risk factor across all ages. Alcohol harms are estimated to cost the NHS around £3.5 billion annually.

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<sup>19</sup> <https://www.alcoholconcern.org.uk/alcohol-statistics> (accessed 20/12/2017)

## Trends in alcohol consumption during the period of the research

The Office of National Statistics regularly report on drinking habits in England.<sup>20</sup> The data in table 1 presents data from 2005-2016 and shows that in 2005 twenty-two percent of men and thirteen percent of women drank on five or more days a week.

Table 1 also shows that the consumption trend is downward overall, and that young people have reduced their consumption whereas older age groups have changed little. A similar picture emerges from data provided by NHS digital (Health and Social Care Information Centre, 2015). They summarise the key points as follows:

- More than one in five adults (21%) said that they do not drink alcohol at all. This has increased slightly since 2005 (19%). Young adults (aged 16 to 24) were primarily responsible for this change, with the proportion of young adults who reported that they do not drink alcohol at all increasing by over forty percent between 2005 and 2013
- The proportion of adults who binged at least once in the week before interview decreased from eighteen percent in 2005 to fifteen percent in 2013. Young adults were mainly responsible for the decrease in binge drinking, with the proportion who had binged falling by more than a third since 2005, from twenty nine percent to eighteen percent.
- The proportion of young adults who drank frequently has fallen by more than two-thirds since 2005. Only 1 in 50 young adults drank alcohol frequently in 2013.

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20 Opinions and Lifestyle Survey, General Lifestyle Survey and General Household Survey; Office for National Statistics (2017)

Table 1 Drinking frequency in the week before interview, by sex and age, England.

	All persons aged 16 and over										Percentages				
	Men					Women					All persons				
	16 to 24	25 to 44	45 to 64	65 and over	All aged 16 and over	16 to 24	25 to 44	45 to 64	65 and over	All aged 16 and over	16 to 24	25 to 44	45 to 64	65 and over	All aged 16 and over
Proportion who drank alcohol on five or more days in the last week															
2005	10	19	28	27	22	5	11	18	15	13	7	15	23	20	17
2006	9	18	26	28	21	3	10	15	16	12	6	13	21	21	16
2007	10	19	27	30	23	4	12	16	16	13	7	15	21	22	17
2008	7	14	25	28	20	3	9	16	15	12	5	11	20	21	15
2009	8	14	23	28	19	2	8	14	14	11	5	11	19	20	15
2010	6	13	21	26	17	3	7	14	15	10	4	10	17	20	14
2011	5	11	22	25	17	4	6	13	14	10	4	9	18	19	13
2012	5	9	19	24	15	2	5	12	15	9	3	7	15	19	12
2013	2	8	18	25	14	2	5	10	14	8	2	7	14	19	11
2014	4	8	21	26	15	1	5	11	15	9	3	6	16	20	12
2015	4	8	18	27	14	2	5	12	17	9	3	6	15	21	12
2016	3	7	15	25	13	2	4	9	13	7	2	5	12	19	10

Source: Opinions and Lifestyle Survey, General Lifestyle Survey and General Household Survey; Office for National Statistics

### Treatment for Alcohol Use Disorders – theory and practice

In this section the most established psychosocial treatment approaches are described, followed by a brief review of the main evidence about their effectiveness. Although there are also medical approaches to treatment, particularly for dependence, these are not applicable to online interventions. The psychosocial interventions described below are suitable for individuals at all levels of severity (if not currently requiring detoxification) but should be primarily offered to harmful drinkers and those with mild dependence (NICE, 2011).

Motivational interviewing (MI) is based on the psychological theory of cognitive dissonance and attempts to develop an alliance between the counsellor and client that promotes a favourable attitude towards change; so that individuals make choices that realistically support changes in behaviour (Miller & Rollnick, 2002). MI was developed from person centered counselling and incorporates an attitude of accepting and validating people's natural ambivalence about change. There are specific strategies or techniques that are used, although practitioners frequently assert that MI is an overall approach and a set of values that override the specific strategies. The key components of MI are: empathy, supporting and developing discrepancies between current behaviour and values (cognitive dissonance), dealing (riding) with resistance, supporting self-efficacy and autonomy. There are treatment manuals and numerous tools designed to promote

these components and a well-developed training and licencing programme for practitioners.<sup>21</sup>

Closely associated with MI is the stages of change or transtheoretical model originally developed about smokers, but widely applied in the alcohol field (Prochaska and DiClemente, 1994) and elsewhere. This model describes stages that drinkers move through sequentially on their way to a non-dependent state. The descriptions of the stages vary, but typically they are “pre-contemplation” where people are not considering change; “contemplation” when they are aware of the problems associated with drinking, but can also see how difficult change might be and what they may lose by stopping or reducing consumption; “preparation” which is active planning for change; “action” is the point of behaviour change; “maintenance” in which they are working to avoid relapse; and the final stage is “relapse” at which point people may start the cycle again. Key features of the model are that ambivalence is assumed and that relapse is included within the model so people, no matter how many times they have not achieved their goals, do not fall outside of the cycle. In alcohol counselling MI techniques are utilised to facilitate movement through the stages and overcome barriers.

Cognitive behaviour therapy (CBT) is a psychological intervention originally developed for treatment of depression and has been applied to a wide range of conditions including alcohol use disorders. It was originally derived from social learning and cognitive theories but, in recent years, has come to encompass a broad range of approaches and techniques. When applied to excessive drinking it may include behavioural and self-control strategies such as self-monitoring and cue exposure, relapse prevention (Marlatt and Gordon, 1985), cognitive change techniques and mindfulness-based approaches.

The Twelve-step programme is associated with Alcoholics Anonymous (AA) and directs people toward participating in groups run by the AA community (Nowinski, Baker, & Carroll, 1992). The approach differs from MI and CBT in that it adopts a disease model,

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21 See, for example, <http://www.motivationalinterviewing.org/>



rather than a psychological one, and promotes complete abstinence from alcohol as the goal. The approach guides patients towards acceptance that they suffer from the chronic and progressive illness of “alcoholism” and that they have lost the ability to control their drinking. Patients are encouraged to acknowledge that there is hope for recovery (sustained sobriety), but only through accepting the reality of loss of control and by having faith that some “Higher Power” can help the individual whose own willpower has been defeated by alcoholism. Twelve-step programmes offer considerable personal support to individuals through members who are also recovering (known as sponsors) and there are also groups for family members. AA is a self-help charitable organisation and does not normally rely on professionally trained therapists.

Social and Behaviour Network Therapy (SBNT) was developed specifically for the United Kingdom Alcohol Treatment Trial (UKATT) and is based on the principle that change can best be made and sustained by developing a positive social network to support that change. It integrates treatment strategies that have been found to be effective in other approaches and brings them together into a manualised treatment approach (Copello, Orford, Hodgson et al, 2002).

The efficacy of psychological treatments has been evaluated in large randomised controlled trials. Two of these, Project MATCH in the United States and UKATT evaluated the relative effectiveness of manualised versions of the main alcohol-treatment approaches. Project MATCH compared CBT, motivational-enhancement therapy (based on MI), and the Twelve-step programme and found that all three approaches were equally effective (Project MATCH Research Group, 1998). The UKATT trial compared SBNT with motivational-enhancement therapy and also found equal levels of effectiveness (UKATT Research Team, 2005).

The development of psychological approaches and the understanding of treatment has not remained static. There has been recent interest in the importance of understanding the therapist–client relationship factors and their part in producing successful treatment outcomes (Cook, Heather, & McCambridge, 2015).

### Screening and Brief Interventions (SBI)

SBIs have been developed for the large group of hazardous and harmful drinkers who would not otherwise access treatment. This group carries the burden of most alcohol-related harm, therefore interventions directed toward this group may be able to significantly reduce the harms associated with excessive consumption. Brief interventions are recommended by NICE as they have the potential to help reduce the aggregate level of alcohol consumed and thus lower the risk of alcohol-related harms for the entire population (National Institute for Health and Care Excellence, 2011).

The elements of a brief intervention are derived from the basic principles of motivational interviewing and are summarized in the FRAMES model (Bien, Miller, & Tonigan, 1993):

- **Feedback** on the risk for alcohol problems.
- **Responsibility**: where the individual with alcohol misuse is responsible for change.
- **Advice**: about reduction or explicit direction to change.
- **Menu**: providing a variety of strategies for change.
- **Empathy**: a warm, reflective, empathic and understanding approach.
- **Self-efficacy** of the misusing person in making a change.

The tools and means to deliver SBIs vary between settings, many of which are opportunistic such as primary care. The most popular screening tool is the 10-item multiple choice Alcohol Use Identification Test (AUDIT; Babor, Higgins-Biddle, Saunders, & Monteiro, 2001). A briefer version, the AUDIT-C, includes only the three consumption questions and has been shown to effectively identify hazardous drinkers (National Institute for Health and Care Excellence, 2011).

The feedback element of a brief intervention may be provided simply as information that informs the individual about their level of risk, or as a more complex and personalised encounter with a trained healthcare professional or alcohol counselor. Similarly, the provision of options about strategies for change may be a printed list or a personal interview. Clearly these are very different modalities, and the full FRAMES approach assumes that the feedback is given by someone with the appropriate personal qualities (warmth and empathy) and therapeutic training (such as in motivational interviewing).

The evidence for the efficacy of SBIs is strong and there have been numerous studies and meta-analyses demonstrating positive outcomes for the approach. Kaner et al. (2007), for example, conducted a Cochrane review that included over 7,000 participants in 24 trials in general practice and five trials in emergency settings. Their conclusion was that after one year or more those people who had received a brief intervention drank less alcohol than the control groups (average difference, 38 grams a week).

This was the state of the evidence during the time I was developing DYD and provided part of the rationale for developing an online version. However, recent large scale pragmatic studies of effectiveness in routine settings have not found the same benefits as those reported in the carefully controlled efficacy studies.

The Screening and Intervention Programme for Sensible drinking (SIPS) were cluster randomized controlled trials in three different UK settings: primary care, emergency departments and probation services. In primary care, brief interventions had no benefit over a simple information leaflet (Kaner et al., 2013). The study in emergency departments, a large, multicenter study, found that it was difficult to implement brief interventions in emergency-department settings for a variety of practical reasons; however, when these difficulties were overcome, they also found no benefits for a brief intervention (Drummond, et al., 2014). Similarly, structured brief advice or lifestyle counseling had no advantages over an information leaflet delivered to offenders by probation officers (Newbury-Birch et al., 2014).

In conclusion there is strong evidence for small and consistent benefits of SBIs; but when evaluated in naturalistic clinical or social settings the same results have not been found. Determining the reasons for these discrepancies is an active area of ongoing research and no firm conclusions have yet been reached. Suggested explanations include differences in staff training between research and non-research settings; intervention integrity and adherence; selection of subjects and the differential impact of the trial procedures themselves, particularly reactivity associated with the burden of the assessments.

A development of the SBI approach has been to include the additional element of referral to treatment after screening (SBIRT). This is most easily achieved within an existing health care pathway rather than in the standalone settings where opportunist screening occurs. Babor, Dell Boca and Bray (2017) recently reported on the outcomes of eleven multi-site studies across different substances that made up the US National Demonstration Programme for SBIRT. The use of different research designs and methodologies made comparisons difficult but, overall, they found clinically meaningful benefits for the programmes and that higher intensity interventions (which generally meant they included extended interventions or brief treatments) achieved greater reductions in consumption, but lower cost effectiveness.

UK government policies have sought to rationally direct the deployment of specialist treatment and brief interventions to make best use of available resources and meet the very large need that the epidemiological data indicates. The National Treatment Agency for Substance Misuse (2006) situated SBIs within a stepped care service delivery model.<sup>22</sup> They recommended the commissioning of simple SBIs (at tier 1) to reduce alcohol related harms experienced by those drinking above recommended levels such as hazardous and harmful drinkers and the commissioning of extended brief interventions (at tier 2) for those with more serious problems who do not require specialist alcohol treatment.

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22 Models of Care for Alcohol Misuse (MoCAM)

## Digital Behaviour Change interventions

The case for providing SBIs online and the relevant evidence base up to 2016 was reviewed in our article for the Oxford Research Encyclopaedia of Psychology (Linke and Murray, public work 11). In this review we make the case that online services have the potential to reach large numbers of people who would not otherwise have access to a brief intervention and that this has been facilitated by the rapid growth of Internet access in those regions where consumption is highest. We also discuss potential advantages of digital such as reducing stigma, low marginal costs and convenience.

The review was an invited “Expert Review” summarising the research literature for an audience of students, professionals and researchers. The abstract, which is reproduced below (Figure 3), summarises the case for digital SBIs, our view of what the evidence base tells us, and questions that remain. The nature of an expert review is that it is open to biases that reflect the authors’ particular knowledge of the literature, their interests and concerns. Systematic reviews are not subject to the same biases and Kaner, Beyer, Garnett et al, (2017) have published a Cochrane review in which they identified 57 studies with a total of 34,900 participants.<sup>23</sup> Cochrane reviews have an international reputation for objectivity and thoroughness as they utilise a methodology that systematically identifies, appraises and synthesises evidence that meets pre-specified eligibility criteria.

The Cochrane review identified digital interventions as those that used computers, mobile devices or smartphones to address problematic alcohol consumption, are responsive to user input to generate personalised content and use some of the same intervention content as standard face-to-face versions. However, the reviewers also pointed out key differences between the two types of intervention. Digital SBIs can be used to provide access to hard to reach groups, whereas standard SBIs are used opportunistically. Digital interventions deliver and record information automatically and users may either miss or appreciate the lack of an interpersonal element. Face-to-face is generally a one-off event,

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<sup>23</sup> This included our own study of DYD (public work number 7) which satisfied all the criteria apart from attrition bias and the HoW study (public work number 9).

whereas digital content can be repeated which may have an impact on long term

## **Figure 2**

### **Abstract**

#### **Internet-Based Methods in Managing Alcohol Misuse (Public Work No 10)**

Alcohol-use disorders are widespread and associated with a greatly increased risk of health-related and societal harms. The majority of harms associated with consumption are experienced by those who drink above recommended guidelines, rather than those who are alcohol dependent. Brief interventions and treatments based on screening questionnaires and feedback have been developed for this group, which are effective tools for reducing consumption in primary care and in other settings. Most people who drink excessively do not receive help to reduce the risks associated with excessive consumption. Digital versions of brief and extended interventions have the potential to reach populations that might derive benefit from them. Digital interventions utilize the same principles as do traditional face-to-face versions, but they have the advantages of availability, confidentiality, flexibility, low marginal costs, and treatment integrity. The evidence for the feasibility, acceptability, costs, and effectiveness of digital interventions is encouraging, and the evidence for effectiveness is particularly strong in studies of student populations. There are, however, a number of unresolved questions. It is not clear which components of interventions are required to maximize effectiveness, whether digital versions are enhanced by the addition of personal contact from a facilitator or a health professional, or how to increase take up of the offer of a digital intervention and reduce attrition from a program. These questions are common to many online behavior-change interventions and there are opportunities for cross-disciplinary learning between psychologists, health professionals, computer scientists, and e-health researchers.

outcomes. Finally, people willing to use technological approaches may be a different population from those attending clinics etc.

In our invited review we concluded that there is some empirical support for the effectiveness of digital SBIs (particularly in student populations). We also pointed out that

the mechanisms of change and the active ingredients of digital SBIs have not yet been identified and we suggested some methodological developments that might provide ways forward, such as utilising factorial research designs and interdisciplinary research projects. The Cochrane review also found that the Behaviour Change Techniques (BCTs) and theories were not well described but was able to address this issue in a more powerful way, by leveraging the statistical power obtained by aggregating the results of multiple studies to calculate the size of benefits from digital SBIs and to compare the different contributions of behaviour change techniques used. Their main conclusions were:

- Participants using a digital intervention drank approximately 23g alcohol weekly (about 3 UK units) less than participants who received no or minimal interventions at end of follow up. Participants who engaged with digital interventions had less than one drinking day per month fewer than no intervention controls and about one binge drinking session less per month
- The BCTs of behaviour substitution (of unwanted behaviour such as drinking), problem solving and credible source (of information) were associated with reduced alcohol consumption.
- The most frequently mentioned theories or models in the included studies were Motivational Interviewing Theory, Transtheoretical Model and Social Norms Theory.<sup>24</sup> Over half of the interventions made no mention of theory.

A consistent concern with online interventions is the “Law of Attrition” associated with trials (Eysenbach, 2005). This “law” states that attrition is normal, rather than a problem, and disregarding data from trials with high drop-out rates may underestimate the benefits gained by those who continue to use an intervention. Nevertheless, researchers have attempted to reduce attrition by overcoming obstacles.

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<sup>24</sup> These are all closely aligned to MI theoretical models

For example, one obvious challenge is to keep up with technological innovations and ensure their acceptability to end users. Crane, Garnett and Brown et al (2017) have user tested a smartphone app that could overcome some of the navigational and useability problems associated with older platforms. The current SIPS Junior trial is also using an app (Deluca et al., 2015).

An innovative approach to improving engagement has been to explicitly embed a digital SBI within the primary care pathway. This utilises a hybrid intervention combining the digital SBI with support or guidance from a healthcare professional. Bendtsen, Mussener, Karlsson et al (2016) have reported on the multi country European ODHIN<sup>25</sup> projects exploring whether take up of a digital SBI was higher if facilitated by a primary care health professional compared to traditional face to face advice. They found that the number of patients screened was no different but a higher number of those who screened positive received advice than at baseline, although this was mostly in the English sample. Overall the level of engagement by both staff and patients with the digital SBI was low.

The EFAR studies are a multi-country initiative involving a series of randomized controlled non-inferiority trials of primary care based facilitated access to an alcohol reduction website. The main results from the Italian study have recently been published (Wallace, Struzzo, Della Vedova, et al. 2017) and have relevance to this review because:

1. The website used as the digital SBI was a translated version of “Down Your Drink.”
2. They utilised an innovative method of recruiting subjects that was well suited to a routine primary care setting.
3. The adoption of the non-inferiority design is novel and capable of addressing the question often asked by policy makers about whether digital SBIs are equivalent to face-to-face versions. It is the design we selected for our own DIAMOND trial (Hamilton et al., 2013).



4. The results draw attention to sample and outcome measurement bias that may pertain to other trials.
5. They succeeded in achieving low levels of attrition.

In this study GPs screened patients and offered them written information about the study along with personal log in details. On entering the site they were presented with the AUDIT-C and given automated feedback. If above the cut-off score they were then shown an image of their own GP and invited to consent and register with the study, complete the measures and randomised to either the digital SBI or face to face. The digital SBI was an adapted version of DYD with the additional function of automated email prompts.<sup>26</sup>

The results showed that at the primary follow-up point of 3 months the two interventions were equivalent. The study also found that 91.5% completed follow-up questionnaires at 3 months and 81.2% at 12 months. These are very high follow-up rates. Despite the apparent success the authors warn about some potential sources of bias. There were fewer hazardous or harmful drinkers in the study than had been anticipated in the original power calculations. This was probably the result of using low cut-off scores in the AUDIT-C at screening; the adoption of higher cut-offs has been argued for by other authors (Khadjesari, White, McCambridge et al., 2017). Additionally, in the face-to-face group the number of hazardous drinkers paradoxically increased at 3 months, but not at 12 months. This may have been due to the final question in the primary outcome questionnaire (the full AUDIT) asking if they had recently received advice from a healthcare professional to cut down their drinking which, of course, is exactly what the face to face group had been discussing in the intervention they had received.

## Conclusions

Excessive consumption is associated with serious health and social problems. Although there are epidemiological data indicating recent reductions in consumption among young people, there remains a need to provide interventions to drinkers who do not access

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26 This feature had been included in earlier versions of DYD

treatment. Brief interventions can assist with this; but the original optimistic view supported by effectiveness trials has not yet been borne out in routine practice. However, studies in the United States, where the interventions are embedded within practice settings and include the option of a referral to a treatment agency, have been largely successful and if replicated elsewhere may be a positive way forward.

Digital SBIs have the potential to reach large numbers of drinkers at very low marginal costs. Studies of their effectiveness are at an early stage, but systematic reviews of the evidence concur that they achieve small reductions in consumption that if delivered at scale could be highly cost effective, whereas traditional methods of deployment are prohibitively expensive. However, online interventions may not be acceptable to all users and service providers and the rates of attrition are high. Research into methods of improving compliance and identifying which factors contribute most effectively to change is required.

## CHAPTER THREE      **Methods**

In this chapter I provide a brief overview of the research methods employed. All the detail is in the published papers that I have included in the thesis, in published protocols or are online in associated *metafiles*. The methods for each study are also briefly summarised in the results chapter where I also include critical reflections on the methods employed in each study. Further reflections on the methodological approach are placed in the discussion chapter (chapter five).

Overall the research adopted a mixed-methods approach. I selected those methods that were appropriate for the stage of the project. The stages were:

- Development
- Evaluation
- Implementation

In practice these stages overlapped and DYD developed iteratively with learning from one stage informing the development of the next. As I shall discuss in chapter five this approach reflects health and medical research methodologies. For ease of explication I shall, however, describe the methods used at each stage and reflect on the process later.

### The methodology to develop the intervention

The principle purpose of DYD was to provide an online version of an extended brief intervention and to do so as faithfully as possible, as well as to exploit the potential advantages that computerisation and the internet provides.

The content of the intervention was determined by reviewing the literature on brief interventions and the treatment of AUDs and identifying the components thought to be most effective (MI, CBT and SBNT). The adaptation for online use was informed by

consultation with experts in online marketing, health informatics<sup>27</sup> and developers of other online health behaviour change interventions (notably heart disease and smoking cessation). The creation of the interactive elements was guided by the principles of enactive learning and the transposing of interactive elements from MI, CBT and SBNT exercises. The overall structure of the material was designed to emulate the stages in a course of therapy and help users move from the stage of “contemplation” to those of “action” and “maintenance”.

The measurement of change relies on self-report questionnaires. Whilst these are well validated offline there was no information about how they perform in an online environment. We assumed that, until proven otherwise, the questionnaires and normative values need not be changed, but should be interpreted with caution. We made the more confident assumption that intra subject changes (test – retest) would be meaningful irrespective of the absolute values and, in fact, Khadejesari et al (2009) confirmed our self-report drinking measure’s test-retest validity in a sub-study.

In all the studies there was some use of Patient and Public Involvement (PPI) to inform the development of interventions and methods. We recruited focus groups and user panels which gave feedback on prototypes or tested the features and kept diaries of their use of the intervention.

### Evaluation

The series of studies evaluating “Down Your Drink” were guided by the Medical Research Council (MRC) framework for complex interventions (see below).

The evaluation studies were:

1. A cohort study to inform:
  - a. Feasibility of recruitment and retention
  - b. Identification of sample characteristics

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<sup>27</sup> Dr Paul Taylor from the Centre for Health Informatics (CHIME) at UCL was a member of the original steering committee

- c. Selection of outcome measures
  - d. Research design
  - e. Estimation of effect sizes for the power calculations
- 2. Optimisation of the Intervention
- 3. Pragmatic randomised controlled trial
  - a. Phase 1 study with stop/go criteria to test recruitment, retention and trial procedures
  - b. Phase 2. Two arm randomised controlled trial.

This complex intervention framework was originally developed for drug trials, but our own innovations and adaptations of the approach for DYD largely anticipated the MRC's 2006 revision of the guidance (Craig et al, 2008) which are suitable for psychosocial, behavioural and policy interventions. The main features of the framework are:

- Identification of existing evidence— development to the point where it can reasonably be expected to have a worthwhile effect.
- Identifying and developing theory — a theoretical understanding of the likely process of change drawing on existing evidence and theory, supplemented if necessary by new primary research.
- Modelling process and outcomes — A series of studies to progressively refine the design before embarking on a full-scale evaluation.
- Assessing feasibility, acceptability, compliance, delivery of the intervention, recruitment and retention to estimate effect sizes in settings where the intervention is likely to be used.
- Selection of an appropriate research design

- Assessment of effectiveness - randomisation should always be considered because it is the most robust method of preventing selection bias
- Measurement of outcomes – deciding which outcomes are most important, which are secondary, and how to deal with multiple outcomes in the analysis. Pre-specification of the analysis.
- Understanding processes - process evaluations can provide valuable insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised.
- Fidelity is not straightforward in relation to complex interventions. Clarity about how much change or adaptation is permissible.

### Implementation

We conducted Formative and Process evaluations as well as randomised trials in selected “real life” settings.

Formative evaluations are designed to identify potential and actual influences on the progress and effectiveness of implementation efforts. These may include the collection of data that inform investigators about actual exposure to the intervention, barriers to implementation and organisational factors and the experience of participants.

Process evaluations are designed to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors. This can be assisted by explicitly stating the theory on which an intervention is based and is addressed in our published review of digital interventions (Linke and Murray, 2017).

The public works that investigated the issues surrounding the Implementation of DYD were:

1. Focus groups with GPs
2. Formative evaluation in primary care
3. Work-based online screening and brief intervention
4. Process evaluation in alcohol treatment agencies

### Introduction

The results section briefly describes the aims and methods of each study and a summary of the main findings. The published papers are attached as appendices. The accounts are followed by critical reflections and the rationale for the next piece of research. An overview and discussion of the findings are placed in chapter five.

### Development and pilot study of “Down Your Drink” (public works 1-3)

Public work 1 describes the development and testing of a printed self-help manual advertised by an alcohol charity in local newspapers.<sup>28</sup> The manual was divided into six weekly parts that could be sent through the post and stored in a blank folder. The weekly instalments were organised according to the stages of change model. The style of writing and the choice of graphics and images aimed to be informative and authoritative, but friendly and encouraging in tone. The manual encouraged users to set their own drinking targets at levels they thought they could realistically achieve.

This study was an attempt to replicate research conducted by Heather et al (1987) who had recruited self-defined problem drinkers via newspaper adverts to receive written information by post. They had randomised half to a self-help manual and a control condition leaflet with general health information. They found benefits for the active treatment group at both six and twelve-month follow-up.

Our result was that only two users responded. To get some feedback two undergraduate volunteers expanded the pool of respondents to forty university students and ten homeless men from an alcohol detoxification centre. Further feedback was provided by volunteer alcohol counsellors who were given access to the manual as part of their

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<sup>28</sup> See appendix 3 for samples



training and some used the materials as a tool in their counselling practice. Informants were asked to rate the manual using Likert scales to rate style, understandability, clarity of information and usefulness. Respondents were generally positive.

Reflection.

This project was badly planned with a very low budget using an opportunistic sample. In retrospect there were methodological problems with the Heather study that should have led us to be cautious. These were loss to follow-up, differential follow up in each group and some individuals who had received other forms of treatment were excluded from the study.

The value of our study was that we now had a self-help treatment manual available for further use. The content had been written by a mix of professionals and volunteers which was innovative at the time. Conducting any kind of research or evaluation was novel in the voluntary sector.

#### The digital intervention “Down Your Drink.” (Public Works 2 and 3)

These describe the development; initial user testing of feasibility and acceptability; and clinical outcomes of DYD.

The structure of the website followed the content, tone and weekly structure of the original manual.

There are different ways a printed manual could be transferred to the Internet. The simplest would have been to store it as Portable Document Files (PDFs) on the Website. To have done only this would have missed the opportunity to make full use of the capabilities of the Internet and exploit its interactivity. We consulted experts in motivational approaches and in human computer interaction and sought partners to build

the website with experience in both website design, marketing expertise and conducting research on the Internet.<sup>29</sup>

The design of the homepage was crucial as it was the first port of call for visitors to the site and, as such, it had a vital role in attracting potential users and directing them towards registration with the programme. Attention was paid to making the page look attractive, relevant, and inviting with few barriers to participation. It invited an active response from the “surfer” and looked like it might be fun to use. The homepage downloaded rapidly (limiting the complexity of the graphics used),<sup>30</sup> had some animated features to maintain interest, conveyed authority by displaying the logos of the hosting organisations<sup>31</sup> and had links to Alcohol Concern” and “Drinkline”. “Buttons” were highlighted on the homepage to find out more information about the site and Frequently Asked Questions (FAQs). The IBA component was presented as a quiz that will “help you decide whether you are drinking more than is good for you” (the FAST screening questionnaire, Hodgson et al., 2002).

As a preliminary to developing the overall design of the homepage (and thereby setting the tone for the rest of the site and the recruitment materials) a profiling exercise was conducted to anticipate the profile of the people the site would be most likely to attract. There was no already available profile of users to adopt and one aim of the project was simply to see who the users were. However, some notions of the likely users would be helpful in guiding the images that could be used, key messages to communicate etc. This exercise formed the basis of the “brief” given to the designers.

This exercise involved describing the unique features of “down your drink” and identifying what the likely motivations of the users would be, e.g. not simply reducing their drinking

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29 Consultations were held with Dr. Steve Rollnick who is an acknowledged authority on motivational approaches and, by email, with Heleen Riper of the Dutch group. Useful advice was also obtained from Paula Lynch and her colleagues at the NCR Knowledge Lab. Our partners in building, hosting and advising on the website was “Worldsites”.

30 Download times were slow and an important consideration at that time

31 The NHS, AERC and University College London

for its own sake, but because they would experience benefits in terms of improved health, family relationships, finances etc. The broad target group for the project was the general public; that was anyone concerned that they were drinking more than was good for them. More specifically, it was hazardous drinkers who had been prompted to move from pre-contemplation to contemplation.

The Briefing provided to the developers is summarised in Tables 2 and 3.

**Table 2. Hypothesised Key Characteristics of Visitors To “Downyourdrink”**

Demographic Factors	Physical Health	Mental Health	Lifestyle	Fears of continued heavy drinking
Age: 30-40 yrs	Not feeling good	Worried	Regular/habitual drinkers	Threat to mental health
Members of a family	Overweight	Under stress	Activities planned around drinking	Threat to physical health
ABC1	Tired/sleeping badly		Everyone around them seems to drink	Threat to marriage or long term relationships
Home computer owners	Hangovers that last all day		Spending money on drink they cannot afford	Threat to family
Male	Stomach pains/digestive complaints			Loss of job

Additionally, we thought that there may be some common experiences that people have relating to their use of alcohol and some experiences that might have prompted them to visit the website.

**Table 3. Hypothesised Experiences of Visitors To “Downyourdrink”**

Experiences relating to the use of alcohol	What may have prompted them to seek help
Alcohol helps to relax, unwind, reduce worries and tension	Felt awful (perhaps all day)
Alcohol increases self-confidence and social success	A bad row with friend, colleague or loved one
Alcohol used as a “crutch”	Received a bad health report
Increased tolerance to alcohol	Financial problems (ATM “eats” their card)
May have tried to stop/reduce before and failed	Missed an important appointment
Nagged by partner or other family member or by friends about drinking	Passed over for promotion at work
Doctor or other medical professional “had a go at them” about their drinking	Offended someone or involved in a fight
	Refused sex by partner
	Couldn't play with the kids
	Caught drinking and driving

A concern we had was that people should not be put at any risk by suddenly reducing their alcohol intake. The site, therefore, prominently displayed messages advising that if anyone had health problems or felt unwell they should speak to their doctors and have medical advice.

Following completion of the screening questionnaire users were given feedback about their responses in both a text and graphics format. Those who scored above the criterion for harmful drinking were presented with information about some of the detrimental effects of hazardous drinking. They were invited to complete the following three questions designed to enhance motivation and were then invited to register with the programme:

A “Is this a good time for you to be thinking about changing your drinking?”

B “On a scale of 1 to 10, how much does your current level of drinking concern you?”

C “How do you feel about learning to change your drinking as of NOW?”

#### Outcome Questionnaires

1. Alcohol Problems Questionnaire (Williams and Drummed, 1994)
2. Short-Form Alcohol Dependence Data Questionnaire (Davidson and Raistrick, 1986).

### 3. Clinical Outcomes in Routine Evaluation- Outcome Measure (CORE System Group, 1988)

Data on the use of the site was collected between October 2001 and July 2002 (public work 3). During the 6-month study there were 7581 visits to the site and 1319 registrations. Of the registrants, 61.8% completed week 1, and 6.0% stayed with the programme until the end.

The site allowed users to record free text responses which provided feedback about the experience of using the site. Examples are included in the published paper. Little information was obtained from those who dropped out, but some reported that the programme was too time-consuming.

#### Reflections

This initial study showed that an online intervention was feasible and attractive to many users. Users were mainly recruited directly via the Internet rather than through recommendation from a doctor. There was a high level of attrition and a range of patterns of use. We were also able to report on the demographic characteristics of users. Those who completed the 6-week programme appeared to improve on the questionnaire measures, but this type of study had not been designed to assess effectiveness. Before conducting an effectiveness trial, we needed to know whether the sample characteristics were likely to be stable, whether large scale recruitment would be possible and collect the data required to estimate effect size that would inform power calculations. This led naturally to conducting a cohort study (see below).

The translation to the online version of DYD was undertaken in discussion with the market researchers and the programmers. This was innovative at the time but focussed on attracting people to the site rather than on maintaining their interest and using it. The process had also been driven by budgetary, time constraints and anxiety about ensuring it worked in a technical sense. Decisions about structure, functionality, images

and tone were taken by subject experts, market researchers and technicians, without involvement of the end users.

A further weakness was that I did not conduct a formal analysis of the qualitative feedback received. A proper thematic analysis would have enabled a more systematic view of the data and reduced the likelihood of unidentified bias in the interpretation. It had not been the intention to look at responses in this way at the outset and we did not anticipate the high number of responses we received.

#### Cohort Study (Public work 4)

Following the initial development work the website was left running and available for use by the public. This provided an opportunity to observe the use of the intervention in a naturalistic setting and learn about who used it.

We analysed 1000 records. The mean age was 37.4 years, there were similar numbers of women and men, just over a third were single and nearly half lived with children. They were predominantly White British and in the higher socioeconomic strata. Over 70% connected to the “Down Your Drink” site from another Internet-based resource, whereas only 5.8% heard about the site from a health or other professional. Much of the Web site use (40%) was outside normal working hours. Only 16.5% of registrants completed the programme and they showed reductions on all measures at week 6.

One unexpected finding was the large numbers of people who registered. Without any further advertising or promotion, it took just over 27 months to complete recruitment of the 10000 users. This provided sufficient encouragement to confidently predict that we would be able to recruit sufficient people for a fully powered effectiveness trial.

The website has continued to be available and there continues to be activity despite there being no active promotion. The data in Table 4 shows that, although declining, there are still new users and people who visit on a regular basis.

<b>Table 4</b> <b>Activity on DYD website 2014-2017</b>				
	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>
Number of sessions*	Not available	14616	9836	7391
Pages per session*	Not available	4.7	4.46	5.5
% New Sessions*	Not available	72.1%	78.9%	74.2%
Number of new registrations <sup>!</sup>	1751	1491	924	842
* Downloaded from google analytics on 11/01/17 <sup>!</sup> Provided by Codeface				

## Reflections

This study was very early in the history of online research and one of its strengths was its innovation in showing that data could be collected automatically, systematically and in a routine way without inconveniencing the user beyond completing a consent form and some questionnaires. However, a weakness was that the analysis plan was not pre-specified, and the statistical analysis was *ad hoc*. The absence of a statistician in the research team meant that we were limited to descriptive statistics and very basic tests of statistical significance (*t – tests and chi-square tests*) and, consequently, lacked confidence in some of the findings. For example, we found that female users, users who were married or living with a partner, and users without children were more likely to complete the programme than men, single users, or users with children. We reported this result in the paper but did not reflect on it in the discussion of results.

The assessment of outcomes relied entirely on self-report. There was no attempt made to validate the questionnaires against other sources of data.

The “cyber saloon” and the “chat room” (where users could exchange views) were not reported on. These spaces were unmoderated, although the researcher has access to the conversations and read them. The facility was only used by a few individuals but was withdrawn when one of the users appeared to attempt to arrange for a meeting in a pub one evening. This feature was not publicly reported. Had it been reported this experience could have been useful to others who were interested in the value or otherwise of online support.

#### The optimised version of “Down Your Drink” (Public Work 5)

In preparation for a full trial we needed to clearly describe and specify the content of the intervention and optimise what we considered to be the active ingredients. This would permit an appreciation of the intended interaction between the user and the intervention. We wrote additional material for the site, restructured and updated the presentation and functionality. The biggest change was to move from a six-week linear programme to a modular approach, whereby users could choose for themselves in which order they encountered the different elements of the programme. The rationale for this was that in the cohort study very few participants saw much of the material, because they had stopped using the intervention, and so that the structure was more similar to the way material tended to be presented on the internet at that time.

In this paper we provided a detailed account of the rationale for the intervention and the process of development. We adopted an iterative process blending literature reviews of Internet interventions for health conditions and brief treatments for alcohol problems, feedback from users of the original site and from users’ panels, and completion of a series of developmental tasks.



## Reflection

The revamp of DYD was a positive development and, overall, I was happy with the end-product. One weakness was the size of the intervention. It could not be considered brief, although many people used it briefly. This meant that some of the most potentially useful features, such as the online drinking diary, could not be easily accessed. Once this problem had been identified we were able to address it by adding some shortcuts to the homepage and suggested pathways/routes for visitors.

The decision to change the structure of DYD was not an evidence-based decision. It was made collectively by the authors of the paper and reflected our experience and opinions. This change meant that DYD was no longer closely modelled purely on a treatment approach and was also not a brief intervention. The advantage of publishing the paper was that we had clearly specified the content, theory and functionality – but it was a hybrid intervention. This later became important when we came to define the active parts of the intervention to assist our analysis of results in the next study.

## Evaluation Studies

### The DYD trial (DYD-RCT) (Public Work 6)

DYD was evaluated in a phase 2/phase 3 randomised two-arm, double blind, controlled trial comparing the optimised DYD website with a non-interactive comparator. The trial was funded for three years by a grant from the National Prevention Research Initiative which was administered by the Medical Research Council (MRC). The methodology is described in detail in a published protocol (Murray et al, 2007) and the full results

published in Public Work 6. There were also sub-studies conducted by different members of the team (listed here under additional publications).

The principal findings of DYD-RCT were that participants at baseline were heavy drinkers and at all follow-up points users reported substantial reductions in consumption. There were no differences between the intervention and control groups in consumption and most of the secondary measures.

There are some distinctive features of the methodology to draw attention to:

- Stop/go recruitment criteria were agreed with the trial management committee at the outset and were easily accomplished. In fact, the success of recruitment became a problem in that more participants were recruited than required and they could not all be followed up within the period of the funding. We therefore decided, for ethical reasons, to extend the availability of the website so that they would continue to have access to the website after the trial closed. The details of recruitment numbers are published in the CONSORT diagram in the paper. The data from phase 2 (the pilot phase) were pooled with phase 3 (the main trial) for analysis at the primary outcome point (3 months).
- Conducting the trial entirely online meant that we had to develop 3 websites:
  - The intervention website (DYD) – branded as an NHS site
  - The control website (non-interactive information only) – branded as an NHS site
  - The trial website for recruitment, consent, randomisation and data collection – branded as a UCL/MRC site.

The implication of this arrangement was that participants first visited the DYD homepage. If they wished to participate they were then directed to the research site and then returned to either the intervention or control site depending on randomisation. Throughout the period of the research participants continued to receive automated emails from the research site.

- All subjects completed the primary outcome measure (consumption), but they were randomised to only one of the secondary outcome measures. This was to reduce response burden and we relied on sample stratification and the large number of participants to reduce potential sources of bias.
- A new measure of alcohol consumption was developed and evaluated for the study (Khadjesari, 2009). Consumption was measured in volume consumed, number of drinking days, days drinking above recommended limits and number of binges.
- A team of specialist statisticians and a health economist led the statistical analyses. They designed the pre-specified statistical analysis plan and dummy tables which included both a per-protocol and an intention to treat analysis. The full trial management committee agreed the post hoc analyses and the decision to compare geometric rather than arithmetic means.

## Reflection

The study was successfully completed and achieved its objective of overcoming the challenges of conducting online research. It spawned a host of subsequent papers exploring the results and is considered to have been a methodological advance in the field. It anticipated the development of the guidelines for the evaluation of complex interventions discussed in chapter 3. The study confirmed our previous finding that there were large numbers of potential users of online interventions with a similar demographic and patterns of site use.

The failure to detect a benefit for the digital intervention is at odds with previous research. For example, a trial by Riper et al (2008) found a benefit for a web-based intervention using a similar pragmatic approach. In this section I outline some possible explanations.

- Naturalistic study with no off-line contact

Our study had no direct contact with participants whereas other studies used newspaper adverts and printed materials such as consent forms. This may have resulted in our population having different characteristics from other studies.

- Treatment seeking population.

Participants in DYD visited the website without prompting. This may have meant that they were motivated to change and may also have used other sources of help that we were unaware of and could not, and did not wish, to control.

- Regression to the mean.

There is evidence that control groups in alcohol treatment trials reduce their consumption by as much as 50% (McCambridge et al, 2014). This may be an effect of a change in behaviour due to being observed<sup>32</sup> or because people seek help at a time of maximum drinking and naturally return to their usual levels after a period.

- Reactivity of assessment

Many of the questionnaires required participants to reflect on their drinking. This meant that the measures themselves could have been a form of intervention that changed behaviour in both groups.

- Similarity of the conditions

For ethical reasons we wished to ensure that information in the control condition was of good quality. Also, to ensure that the two conditions were comparable in all ways apart from interactivity, we used the same authoritatively styled branding and NHS and UCL logos.

The number of responses (clicks) required of the control group meant that the so called “flat” site was highly interactive itself. This contrasts markedly with other

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<sup>32</sup> “Hawthorne” effect

studies that may have used a leaflet or downloadable pdf information sheet as the comparator.

- “Dose”

It is conceivable that intervention group participants did not complete enough of the site to experience potential benefits. The effect of “dose” was analysed in the study and there was a significant difference in the number of visits and pages downloaded between the two arms; but this had no impact on outcomes.

However, we do not know what a sufficient dose would be or whether the key issue is which pages were visited (rather than how many) and whether exercises were completed.

The DYD-RCT was a three-year project costing £350,000 of public money on top of money that had been spent on previous projects and additional un-costed expenses for users and others (McCambridge et al, 2010). We felt a moral obligation to ensure that the public benefited from this endeavour. To this end the eHealth unit at UCL has generously continue to fund DYD so that it remained a resource for public use. Too often digital interventions have been taken down once a trial had been completed.

The overall interpretation of the results has had important implications for what happened next. The statisticians in the team considered the findings to mean that DYD was ineffective. DYD had, in their view, “failed”. The clinicians took the view (common in psychological therapy research) that a lack of evidence for effectiveness is not evidence of a lack of effectiveness and the DYD project could, and should, continue.

We now had extensive experience of DYD and there were no indications that it was at all harmful. Set against this was the “opportunity cost” of participants’ time and effort and the risk of engaging with something ineffective; however, people were free to use other interventions alongside DYD and information on DYD signposted people to other resources. However, as we had not explicitly assessed harms, and as clinicians who had

developed the intervention we were keen to see it succeed, we could have underestimated any risks.

Research conducted by Khadjesari et al (2015) indicated that DYD was valued by users and provided a service that was not otherwise available. They had interviewed a sample of users about their use of the site and conducted a thematic analysis. They found that this group had identified themselves as having a problem but were wary of being classified as an alcoholic. They wanted help but were unwilling to talk to anyone directly, so the privacy of the internet suited them. They were also pleased to find a service that allowed moderate drinking rather than just total abstinence.

The DYD team were aware of a high level of demand and the lack of available treatment facilities. On this basis we explored how digital intervention could be evaluated in different applied settings.

### Implementation Studies

The four studies in this section are thematically linked. They are all attempts to explore the barriers and facilitators to implementing digital interventions in real-world settings. The first two were early attempts in primary care and we conducted the first of these at the beginning of the DYD project. Both studies have methodological weaknesses, but their value lies in charting ground that other researchers have followed. The third and fourth studies are methodologically stronger and open areas for future research and development.

### Acceptability in General Practice (Public Work 7)

This study explored GPs attitudes towards digital SBIs in their routine work. We conducted two focus groups with local GPs and asked them to review DYD materials and then discuss open ended questions about their approach to alcohol related issues that

presented in their surgeries. The discussions were conducted by myself and themes were extracted by RH and reviewed by PW (who was not present at the focus groups).

The themes indicated that GPs were reluctant to ask their patients about drinking, were dissatisfied with local treatment services and thought that there were many barriers to patients engaging in treatment. They were cautiously positive about using a digital approach. Anecdotes given by participants revealed some of the complexities. For example, several mentioned that they did not wish to record a patient's drinking in the notes as it might affect their chances of getting a life assurance policy or health insurance. Others thought the published consumption guidance was too restrictive. For example, making (possibly deliberately humorous) statements such as that a patient only had a problem if they drank more than their GP did, or if they were drinking good quality whisky they were probably OK. Another common observation was that they were reluctant to mention alcohol consumption as a problem because it might upset the patient or because there was no local service to refer to (a difficulty that could be partially solved by a digital SBI).

## Reflections

This study was conducted before we had funding for DYD-RCT and limited by the lack of a budget to transcribe the discussions and conduct a formal analysis. There were other methodological weaknesses. The GPs in the groups were unlikely to be representative of most GPs as they were recruited through an academic network associated with the university. Although the focus groups' discussions were fulsome and wide ranging there had been no attempt to utilise standard qualitative research processes such as continuing to saturation. The focus group facilitator was not neutral but had a strong commitment to digital and standard SBIs. This was made clear to the focus group members and may have influenced the discussions, although this potential for bias was partially mitigated by having an independent researcher carry out the analysis. Nevertheless, the themes that emerged in the study appeared to have face validity and resonated with the researchers

who all had considerable experience of implementing innovations in primary care. As such this project was helpful in guiding future implementation projects.

The original publicity for DYD had included adverts in GP magazines and leaflets directly mailed to surgeries; but very few participants reported that they had heard about DYD from their GPs. The results of this study may help to describe some of the barriers GPs experience in discussing drinking with their patients.

There is a growing literature on the acceptability of SBIs in primary care, but this is beyond the scope of this thesis. One study, however, in which I am a co-researcher, suggested that patients' attitudes may mirror some of those found in GPs (Khadjesari et al, 2017). Users of DYD, for example, did not see themselves as being vulnerable to alcohol related harms even though they knew themselves to be drinking above recommend safe levels.

#### Formative Evaluation in Primary Care (Public Work 8).

This was a natural uncontrolled experiment. A Primary Care Trust invited me to deploy DYD in their locality and I used the opportunity to set up a pilot study and conduct an evaluation. It was designed as a clinical service that could be delivered by staff trained in facilitation skills, but without having specific training in alcohol or other substance misuse. Using a mixed-methods approach the aim was to determine the feasibility and acceptability of the service, describe its effects on users and the costs associated with implementation.

The response to the project was mixed. Despite support at senior levels it was challenging to implement in practice and referral and response rates were low. There were difficulties in supporting the facilitator at distance and internal changes within the organisation were disruptive. However, the study produced some informative data. Practice staff reactions were similar to those of the GP focus groups, access to computers was difficult for some patients and non-English speakers required extra support. Some



patients liked the anonymity of the digital approach and, therefore, were reluctant to be interviewed.

Reflections.

This was a “real world” study with “real world” problems. It is possible that more was learned from the struggles of implementation than would have been learned if it had gone smoothly.<sup>33</sup>

The overall outcome, however, has been positive. The commissioners have persisted and adopted the implementation of their own copy of DYD. They have made it openly available without referral and have joined with colleagues in the Alcohol Health Network to introduce a different intervention and are continuing to audit its use.<sup>34</sup>

The implication of this experience is that it may take time to learn and adapt before the right model for a setting is found. Support and leadership from individuals with determination to see a project through is vital.

#### Health on the Web – a workplace study (Public Work 9)

In this study the intervention was a brief SBI embedded in a digital health check offered to employees from a large private sector organisation. DYD was as a backup resource for those in the intervention group. The design was a two-group online individually randomised controlled trial.

A concern about the DYD-RCT had been that artefacts of the study procedures – specifically selection biases, reactivity of assessment and Hawthorne effects - may have had an impact on the results. In this trial we attempted to reduce these risks of bias by

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33 The challenges were similar to those I have experienced in setting up psychology sessions in GP practices in my NHS role.

34 I am a member of the AHN advisory board

collecting health-related information and the AUDIT-C prior to randomisation. Consent was obtained to collect information rather than to participate in research. The specific alcohol measures were collected at follow-up.

The main outcome of the study was that there were no differences between the groups. This finding is at odds with other published studies and we looked closely at our data to see if we could explain this result. It was evident that we had recruited a relatively healthy group of staff who, although drinking above the cut-off level of the AUDIT-C, may not have been heavy drinkers. To test if this was a factor we conducted a post-hoc analysis of those with higher scores, but still found no differences.

## Reflections

This was an ingenuous study that attempted to overcome some of the difficulties of interpreting the results of the DYD-RCT. Nevertheless, it was another unexpected negative finding.<sup>35</sup>

The setting for this study was a company that had recently conducted staff health campaigns, including about alcohol, and staff may have participated in these and those who were concerned about their drinking already made reductions. It is also possible that interventions for the other health behaviours may have generalised to drinking. Placing the routine data collection at the “front door” of the intervention may have resulted in reductions in consumption before randomisation.

The participants’ self-reports suggested that they had healthier lifestyles than the general population. They may, therefore, have not been experiencing any negative effects of their drinking so lacked motivation to change.

Finally, this study, like the others in this research project, indicated that there was a demand for access to the intervention; but we do not have data on how many people

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35 Also included in the Cochrane review (2017)

actually read the feedback they received. Also, only a small percentage went on to look at DYD; but we did not collect data about their level of participation with the materials.

#### The DIAMOND Trial (Digital Alcohol Management ON Demand) (Public Work 10)

This research was directed at a key question about digital alcohol interventions. Are they as effective as interventions delivered face-to-face? We adopted a mixed methods approach which included a pilot randomised controlled non-inferiority trial that would test this; but we did not know if such a trial would be feasible to conduct. This paper reports a process evaluation and thematic analysis of interviews with alcohol counsellors.

The study was part of the CLARHC collaboration and a description of the programme and interviews with me and colleagues about the research are available on the CLARHC website.<sup>36</sup> Recruitment was from community alcohol services in North London.

I redesigned the digital intervention especially for the study. To emulate a typical course of counselling it was structured into six weekly sessions and, in an attempt to improve adherence, elements of gamification were introduced by adding case studies and video clips.<sup>37</sup> The intervention and research portals were tested by patients' representatives.

Recruitment to the study was low suggesting that community alcohol services were not suitable places to recruit for a full trial. The low recruitment was because many of the service users were too severe to be included. The interviews with the counsellors threw additional light on the issue. They thought that clients did not opt-in to the trial because they preferred one of the options and did not wish to be randomised. The counsellors preferred face-to-face which may have influenced recruitment as well.

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36 [https://clahrc-norththames.nihr.ac.uk/behaviour\\_and\\_engagement\\_with\\_care\\_theme/diamond-digital-alcohol-management-on-demand/](https://clahrc-norththames.nihr.ac.uk/behaviour_and_engagement_with_care_theme/diamond-digital-alcohol-management-on-demand/)

37 HeLP-Alcohol

## Reflection

This study reiterated themes from previous studies. Namely the challenges staff face offering the intervention, the practical issues of embedding a service into routine practice and high levels of drop out. Additionally, the challenges of settings not used to research had to be addressed.

The challenge of integrating the intervention into routine settings required considerable groundwork by the research team of academics and professionals. Feedback also suggested that team managers found it to be an additional burden that was not welcomed.

The unexpected learning came from discovering the high proportion of clients with complex needs attending the services. Community services were originally commissioned for a less severe group and it was helpful for the commissioners and public health professionals in the research team to see this directly for themselves, as well as reading about it on research reports and formal feedback.

We have now extended this approach to a second study, but this time recruiting from a hospital Emergency Department. As previously, there was drop out. This paper is currently in peer review, but our conclusions are that participants were not at equipoise as they wanted to try the website and were disappointed to be randomised to face-to-face, so they were less engaged and dropped out. Other reasons for drop out included not accepting that they had a drink problem; problem drinking interfering with their ability to take part in a trial or forgetting appointments; having a busy life and being randomised to Treatment as Usual made it difficult to attend appointments.

## CHAPTER 5 Discussion

In chapter one I described the interlinked contexts which I see as framing the DYD project. These are the Science, Public Service and Personal contexts. Over the course of this work these contexts changed. Writing this thesis has enabled me to step back and pay attention to some of the changes. In this final chapter I describe what these contexts were, how they changed and suggest ways these contexts may have influenced the directions DYD took.

I begin the chapter by describing each of the contexts separately, in their own terms, as if they were independent of each other, and follow through the implications of the changes as I see them on this work. I then reflect on them together and hope to show that, whilst all have a legitimate claim to have been influential, it was the combination and cross-fertilisation of these themes that was the most powerful shaping force and suggest that much pragmatic, health science research is often a bit like that. I then go on to make suggestions about the direction that future developments could take.

### The Science context

The scientific method was the formal paradigm for this work and “evidence-based practice” a mantra throughout. The complex interventions framework we followed was centred around “definitive” trials and other methodological approaches were garnered in support of these. The essence of this approach is that conclusions from one study should lead to the research questions of the next. This is the stuff of research grant applications. Other influences include research calls on particular topics based on needs identified by senior figures in research councils and the interests of the members of research groups who are often university based.

The RCT is ubiquitous in healthcare, but the rationale for adopting it is not always clearly articulated. In this case we wanted to find out whether DYD “worked” and if so for whom and in what circumstances. We wanted to be able to transparently communicate findings

to others so that they could understand and replicate the studies. Our intentions were to influence healthcare practice, and trials developing evidence are one accepted way to achieve this.

The results, however, did not provide the clarity we sought. The DYD-RCT did not demonstrate benefits for our digital intervention, although other researchers in their studies, using similar content, have published strong data of effectiveness. We sought to account for this variability and my conclusions are described in chapter four. We also looked to identify research designs that are better suited to the context in which the intervention is intended to be used. For example, in the DIAMOND study we planned to conduct a non-inferiority trial because we want to know whether DYD is as clinically and cost effective as Treatment as Usual (TAU). This is an important question for service delivery.

There are further questions beyond effectiveness that scientific research could address, and these can also utilise research designs other than a two-armed controlled trial. A key concern is which aspects of digital SBIs are active. Clinicians have made suggestions, there is evidence from literature reviews and the Cochrane review's conclusions have lent empirical support to some of those. The relative importance of these elements requires empirical investigation; but large-scale trials are expensive, lengthy and complex to conduct. An alternative is to utilise dismantling factorial designs, comparing elements separately, which more efficiently use the subject pool and require fewer participants to achieve the required statistical power. A barrier to this is that digital SBIs are complex interventions and the components are generally not well described. This needs to be rectified before such studies can be conducted.

Intervention "stickiness" is an issue for online interventions as attrition is the rule rather than the exception (Eysenbach, 2005). If users do not view important aspects of the programme or complete the components they cannot be expected to be influenced by them. Incentives have been offered to encourage people to complete outcome questionnaires in research, but their use in encouraging engagement with the intervention has not, so far, been explored. There is also an interest in "gamification" to

encourage participation and this was introduced to a limited extent in the HeLP Alcohol iteration of DYD but has not yet been fully tested. An ongoing study by the SIPS research team has introduced gamification in “SIPS Junior” - their app for young people (Deluca et al, 2015) – but the results are yet to be published.

The user voice played a role in this research programme but had only a small part. At the time of the early studies the main approach to user involvement was limited to helping to design health information leaflets written by professionals and attending meetings as representatives. This has changed radically, and PPI and coproduction are now central to research activity and grant applications, with user representatives having a much greater impact on key decisions about funding, research goals, ethical and other issues. A more active voice for the user might have changed not only the content and functionality of DYD but also, perhaps, radically changed the intervention itself and created a completely new one. Additionally, a strong user voice may have influenced the goals of the research programme and the way it was conducted.

A definitive feature of RCTs is that user choice is eliminated. The DYD deployment studies suggested that users have their own views about which interventions they prefer and conducting preference trials that allow choice may get different outcomes.

The conduct of RCTs became increasingly regulated during the period of this research. The publication of the CONSORT frameworks in 2001 and 2010 set high standards for reporting RCTs.<sup>38</sup> Another development was the requirement to publish protocols and specify analysis plans in advance of collecting data. Any deviation from these standards has to be transparent and explained. The impact on DYD was that the trial was seen by the research community to be well conducted and the results published in a prestigious journal. A possible downside, however, was that *post hoc* exploratory analyses of the data were limited, and because the data was handled by statisticians and processed automatically by computers, the ability of members of the team to “eyeball” the raw data and make intuitive deductions was not possible. Informal analysis and close contact with

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38 <http://www.consort-statement.org/> (accessed 28/2/18)

the data, as used to be the practice, may have generated new hypotheses about how the intervention was being used.

The original rationale for digital SBIs was predicated on the success of the face-to-face versions. The disappointing outcomes of studies such as the SIPS trials has provoked a wider debate that has possible implications for online interventions. Heather (2014), for example, argued that policymakers have been too quick to implement brief interventions, doing so before they had done the necessary foundational research in the real-life settings to maximize their effectiveness. Cook et al (2015) have emphasised the importance of relational issues in delivering SBIs. The personal aspect is clearly missing in automated formats, although some users may prefer this anonymity and remoteness. The user feedback we received in DYD, however, did include examples of users appreciating and commenting favourably on the writing style. It appeared that they approved of the authoritative, but non-judgemental, attitudes they perceived in the text which was consistent with the style of the motivational interviewing approach. Furthermore, there may also be individual differences in response to digital SBIs, beyond demographics, that are worth examining in future studies.<sup>39</sup>

A question that sits alongside the specific aspects of the research activity is how well did the scientific approach serve the project as a whole? The research designs utilised mixed methods, but overall trial methodology was dominant. Did this appropriately shape the direction of the project or did it lead it in directions that were not useful or even counter-productive?

Medical research, which favours the RCT as the “gold standard”, is not the only paradigm within scientific methods. Murray et al. (2016) point out that engineering and computer scientists typically employ multiple cycles of development and would not normally evaluate a product until it was relatively stable (known as UX design).<sup>40</sup> Interdisciplinary

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39 For example – familiarity with the online environment, personality variables, choice

40 See, for example, <https://www.interaction-design.org/literature/topics/ux-design> (accessed 13/3/18)



approaches could help ensure that expensive RCTs are not undertaken too early in the development and evaluation of a digital intervention.

There is insufficient space to discuss in full varying definitions of science, which scientific approaches are privileged over others, the role science plays in determining healthcare decisions and the role of interest groups in influencing what research is funded. I will restrict my comments to a few aspects that directly influenced DYD.

The funding was primarily from research councils who set priorities, quality standards and required research to be of publishable quality in high impact journals. Significant funding is available for RCTs and little else. Our research council funding enabled and shaped the project. Had the funding bid failed (as many submissions do) then the research team would not have come together in the way that it did with the consequent cross fertilisation of ideas and DYD would probably have retained its original format.

The project was hosted within the *eHealth unit* at UCL which sat within the Primary Care and Population Sciences department of the medical school. The unit's *raison d'être* was to undertake clinically relevant research and there was a strong tradition of conducting clinical trials. The prestige of the unit facilitated the involvement of researchers with international reputations and the success of the DYD research supported the growth and influence of the unit.

Without the publication and timescale pressures, however, and the need to tie the intervention into pre-existing substantiated theories, there might have been greater opportunities to have explored more creatively different versions of the website. There might also have been space for more qualitative methods and user involvement. Perhaps, as both Murray et al (2014) and Heather (2014) imply, projects fail because of the rush to conduct trials and insufficient primary work is done. In recent years the unit has more fully embraced a broader approach to research.

Finally, what if there had been funding streams from outside of the scientific paradigm? These may have focussed on extraneous outcomes such as service provision or attracting

“traffic” for different purposes. Whilst these may have utilised the tools of science they would not necessarily have maintained the required equipoise about results that the scientific approach requires.

In conclusion it would appear that the specific requirements of the modern approach to doing science strongly influenced the direction the DYD project took - but also enabled it.

### The Public Service context

At the outset of the DYD project there was little in the way of published guidance available about interventions for hazardous and harmful drinkers. In fact, this terminology was not in use then. Initiatives with goals of prevention, such as DYD, relied on extrapolating from existing treatment approaches and methods. Subsequently NICE have published guidance recommending SBIs as part of healthcare pathways (2011).

The influential Wanless report (2002), among others, predicted that demands for healthcare would outstrip capacity. The proposed remedy was to adopt a public health prevention approach and promote changes towards healthy lifestyles and the expansion of self-management approaches to managing chronic conditions. The report also promoted the utilisation of new and emerging technologies. Similarly, the Expert Patient Programme promoted self-care for people living with long term conditions. This was the policy context in which DYD took shape. The aim of DYD at the outset was primarily to provide a free to use, accessible, public service and it was the first in the field (certainly in the UK) to do this digitally. The programme of scientific research was initially secondary to this.

Public service values promote equity of access and it is important to test digital interventions against this criterion. To date this has not been routinely attempted and is difficult to do so retrospectively because most outcome trials have not reported user characteristics in sufficient detail. Data from DYD, however, was reported and it showed that the cohort were largely in their mid to late thirties, defined themselves as white and well educated. This age group is younger than the cohort currently most at risk from

alcohol related problems. Future research should take care to address this issue and conduct equality impact assessments using recognised tools.

The “digital divide” – the economic and social inequalities arising from differential access to information and communication technologies – also bears on this issue. During the period of the research this divide has narrowed and digital literacy increased, particularly among younger people. There has been an increase in the availability of free Wi-Fi in public areas and an increase in mobile phone use meaning that more people have access to the internet. However, people also need to be able to afford a smart phone or tablet. Developers of interventions follow these consumer trends and it may mean that in the future underserved and marginalised groups get left behind.

The take up of digital SBIs and levels of compliance have been low, and it is not clear that the interventions are effective enough to warrant all the effort involved in creating, deploying and maintaining them. Although economic evaluations have sometimes been attempted, there is, as yet, no evidence that the anticipated cost benefits have been realised.<sup>41</sup>

Health and social care economies are currently under enormous pressure of demand and it is not uncommon for NHS services to be decommissioned and replaced by third sector organisations. One pertinent observation from our DIAMOND study was that recruitment was difficult because of the complexity of the problems experienced by the service users attending community services and they were not, therefore, eligible for the study. The implication is that those with complex problems were attending community counselling services rather than mainstream NHS facilities.

The current position is that ambition for digital technologies in various forms permeates NHS strategy documents and there is a new digital health care “industry” which is seen as both a solution (possibly a panacea) to health care delivery problems and as source of

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41 See narrative synthesis in the Cochrane review. This is possibly because the economic evaluations were conducted in trials that showed no reductions in consumption.

economic growth in the technology sector. NHS strategy proposes that digitally enabled care is to be used by most citizens by 2020 (Health and Social Care Information Centre, 2015). The field is no longer the preserve of academics, charities and public-sector bodies. Digital Health London, for example, have created an “accelerator” programme matching NHS providers with technology “start-ups”<sup>42</sup> and giant internet companies such as Google have made their ambitions in healthcare clear.<sup>43</sup>

The move to digital is not without controversy. There are anxieties about the security and accuracy of personal health data, the potential for misuse and concerns about the use of “big data” to generate decision making algorithms that have an impact on access to treatment and choice.

Experience with DYD has thrown up some related issues that could usefully be incorporated into this debate.

- The costs of providing computer equipment and an internet connection are borne by the end user. In a sense this means that a fully digital service is not entirely free at the point of demand which has been an important principle enshrined in the NHS constitution.
- The maintenance of the website falls to private companies and arrangements for secure procurement are not yet in place. Costs may increase over time and service providers are dependent on these companies for service continuity. There are costs involved in keeping projects up to date and accommodating a range of technical changes outside the control of health or other public service providers. Taken together these variables can leave digital services vulnerable. A worst case, but entirely possible, scenario is that a digital treatment service could be taken down whilst people are using it.

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42 <https://digitalhealth.london/accelerator/> (accessed 28/2/18)

43 [https://www.google.com/intl/en\\_us/health/about/](https://www.google.com/intl/en_us/health/about/) (accessed 28/2/18)

- Intellectual Property Rights are not always clearly defined or attributed, which may affect how products are developed and made available to service providers.
- Researchers and developers may need to create business models and organisational structures to ensure fidelity to the evidence base and intentions of projects.
- Funding streams, particularly from Industry, may result in a conflict of interest. For example, there has been controversy about the role of Drinkaware who provide a digital SBI on their website (McCambridge, 2014).
- The potential for commercialisation may lead to misuse. A specific experience from DYD was that we found “cyber squatters” using similar domain names selling products and diverting traffic from our intervention. Another example was finding tools from digital SBIs on websites selling car insurance which also directed site visitors to a company selling home brewing equipment.

On the other hand, integration into wider contexts may provide opportunities to incorporate opportunistic digital SBIs into a wide range of public service settings, healthcare pathways and even commercial settings such as online shopping or social media.

#### Personal factors as context

In chapter one I recounted the story of DYD, relating autobiographical material and key events that shaped the project. In this section I reflect on the same material, but thematically, drawing out the larger story of the way the project and my personal approach developed, with the intention of identifying themes of broader interest.

The early projects were characterised by a desire to create something new that would reach beyond just those drinkers that could be helped by individual practitioners. It was part of a wider approach of “giving psychology away” so that the benefits of the approach could be spread more widely. This involved staff training, manualised treatments, and organisational development and consultation. My involvement with ASP&W was an example of this approach.

Clinical psychology at the time was a new profession establishing its identity and role. This was very clear in the new service in Pontefract that I worked in where two of us covered all the specialities in the health district. It was obvious that to have a significant impact we would need to move beyond individualistic approaches and develop ways of working that would affect whole systems and groups of staff. The result was that I was encouraged by my manager to spend some time on research and project work. Later, when I moved to London, I joined a department with close ties to universities where research activity was supported even though I had a predominantly clinical role. This has changed. The current professional climate and managerial culture, and the impact of “austerity” on public services, has narrowed the scope of professional roles. Psychologists are often employed primarily as therapists who deliver treatment and occasionally consultation. There are set activity level targets and few opportunities to spend time developing projects or conducting a programme of research. It has always been the case that psychologists have been trained as therapists; but increasingly it has been by further therapy training that has been the main way in which psychologists have sought to improve their practice, and the advanced research skills they have acquired are rarely utilised.

The opportunity to consistently develop research skills throughout my career has, I believe, had a beneficial impact on my capacity to undertake and support clinically relevant research in the NHS.<sup>44</sup> Having had personal experience of conducting different types of studies I am now in a better position to critically evaluate the evidence base for

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44 This is not just in the alcohol field but also in psychological therapy and mental health generally; by my own research and of colleagues and students I have supervised.

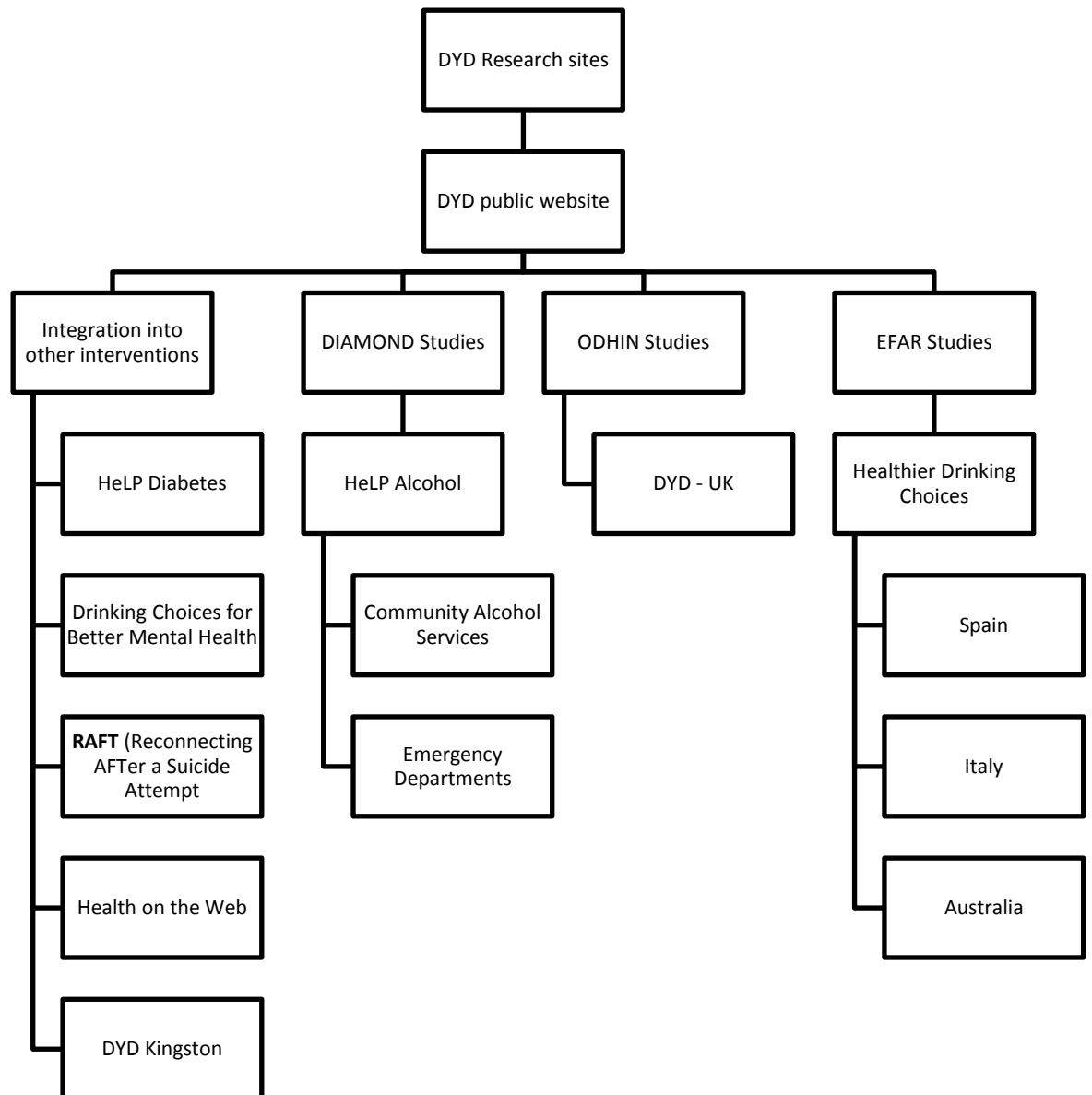
what we do and understand its limitations. Conversely, the clinical skills and experience of being a practitioner has informed this research and, hopefully, guided it towards applicability and relevance. This is the model of the clinical academic which seems nowadays to be possible only for senior staff (usually doctors) who have track records of attracting significant research funds.

The research journey has brought me into contact with many highly experienced and talented colleagues and mentors that I have been fortunate to learn from. Through them I have been exposed to enriching ideas and opportunities that I would otherwise have missed. What began as an individual research interest evolved into a programme of research conducted by teams made up of experts from complementary health science disciplines. This reflects a wider trend in health service research. Individual projects are more likely to progress when they are linked to a broader set of aims and interests and are conducted by teams of researchers and supported by relevant interest groups (stakeholders). DYD benefitted from fitting in with the digital *zeitgeist* and in recent years there have been research council “calls” encouraging more research to contribute to the field.

The position of researcher has also enabled me to contribute to the wider policy context by means of bringing the evidence base to policy makers’ attention. For example, in my local NHS context I have introduced digital SBIs into routine services and have led the Digital Innovations group which covers many clinical digital interventions and not just alcohol related ones.

## Conclusions

Fig 3 The DYD Family Tree



To my knowledge DYD was the first fully on-line digital intervention aimed at reducing alcohol consumption and associated risks. It was a team effort and my colleagues have all made important contributions to the field. The DYD website has also had a life of its own beyond that of its originator. It has been integrated into other interventions and used in others' research. The ones I am aware of are presented in the DYD family tree in Figure 3.



Together with research teams headed by Kypros Kypri in Australia and John Cunningham in Canada, DYD spurred a twenty-year research enterprise that is now reaching maturity, but not completion.

Digital Interventions began with “proof of concept”, moved through testing and evaluation phases and research is now grappling with the challenges of deployment, effectiveness in real world situations and identifying which components contribute to behaviour change.

There have been disappointments along the way. The initial one was the failure in our trial to find an effect; but our analysis of the possible reasons for this helped in the planning of further work and developing research designs. Another was that only a few individuals made full use of the intervention. A key challenge for the future is to develop strategies that more effectively engage users and identify who benefits most and in which settings.

The collective weight of the research, along with official concern about the detrimental impact of heavy drinking on public health, has meant that, in the UK at least, digital interventions are now part of public policy. For example, in recent years it has been a major part of the work programme of the South London Health Innovation Network.<sup>45</sup>

Reflecting on this work as a whole, I have come to see that the particular story of DYD reflected a larger narrative of how health science research gets done. From my individual perspective I took up the opportunities that were offered to me, worked hard to promote the project where I could and aligned the objectives with the prevailing *zeitgeist* when necessary. However, there were larger forces at play. In chapter one I described how important it was in DYD’s development that it included all the different types of knowledge described in Freeman and Sturdy’s (2014) conceptualisation. Elsewhere I described the role research councils play in determining which projects and types of

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45 <https://healthinnovationnetwork.com/?s=alcohol> (accessed 10/3/18)

research activity get funded. I have also considered how the interests of influential individuals in public office, the overall policy context and the freedom, or otherwise, of professionals to follow their interests have played a role. These factors were crucial influences on the way DYD developed. Overall these influences helped ensure that DYD was relevant to the various interest groups whose support was required along the way. I was fortunate that my personal career history, values and professional training, along with the expert knowledge and experience of my collaborators, brought all this together.

### What next for Digital SBIs?

To use an apposite metaphor the cork is now out of the bottle. Digital SBIs are widely available and promoted by a range of different organisations. However, data from my own studies and that of researchers elsewhere (such as the ODHIN trials) indicate considerable difficulties with implementation and engagement. I will briefly discuss two hopeful directions for future development that may improve this – Blended Interventions and Tailoring.

Blended interventions refer to the combination of digital tools with another approach – usually face-to-face. This has been developed in the mental health field where online CBT modules replace some of the traditional therapist contact. This partially addresses the loss of the relationship element in digital SBIs that was pointed out by Cook et al (2015) and the EFAR trials suggest that blending may be a promising approach in primary care.

I have recently adapted this approach for use in mental health services. “Down Your Drink” has been renamed<sup>46</sup> and integrated into the care pathway for people who drink heavily in a secondary care mental health service. As with ODHIN and EFAR service users are given unique log-in details by a practitioner and told they will be followed up. Once logged in they are invited to complete the AUDIT-C, receive feedback and are invited to register. At the outset they are told that their practitioner will not be able to see the

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46 Drinking Choices for Better Mental Health.

details of their responses, but only information about when they log in and which pages of the site they visit.

Tailoring refers to structuring an intervention so that users are guided to see those parts that are most relevant to them. This is based on information provided by the user at the outset and is a standard element of tailored health education programmes. The data does not yet exist for alcohol programmes beyond simple stratification for levels of consumption and risk, so in DYD we offered users suggestions about how they may choose pathways through the material. In my mental health project users are categorised according to which problem area they identify with.<sup>47</sup> These are currently Depression, Anxiety, Post Traumatic Stress Disorder, Psychosis and Age; but there is scope to include more. After registration all users are shown an initial short introductory video from the medical director which is then followed by the topic specific video by a doctor or psychologist and some relevant written material to “click through” according to their choice of module. This pilot project is currently at the stage of feasibility and acceptability testing. One key issue to address from the outset is how this type of intervention could be routinely deployed in services which are highly complex systems. This is an issue for implementation science and a series of interviews with frontline staff are being planned to investigate this.

Another way in which both Blending and Tailoring can be considered is integration with other online interventions. This was attempted in the Health on the Web study but DYD was rarely used by participants. Currently DYD forms part of other eHealth interventions such as programmes for diabetes, sexual health and for after self-poisoning. Future research could consider whether effectiveness is affected by this type of integrative approach.

Integration is likely to be an important future consideration in the deployment of digital SBIs and the provision of a range of options would seem appropriate. There appears to

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<sup>47</sup> Including but not restricted to diagnosis

be a demand for stand-alone options as indicated by the qualitative studies with DYD users (Khadjesari et al, 2015) and the success of the SBIRT studies (Babor et al, 2017) suggests that digital SBI's could be part of referral pathways. Practitioners could use digital tools to support face to face interventions. Not everyone will be happy with a digital approach or have access to them, recruitment has been challenging in both on and off-line situations so adequate services providing a standard approach should also be available and not totally replaced by digital interventions.

Research into digital SBIs may benefit from learning from other digital behaviour change interventions. The most likely candidate for this is smoking cessation, but the differences between the health messages (stopping for smoking and harm reduction for drinking) make direct comparison difficult; although methods of recruitment, utilisation of gamification, off line messaging etc. may be similar. Additionally, research into which BCTs are most effective in alcohol interventions (such as those identified in the Cochrane review) will continue to have an impact on development.

The field of online interventions for health behaviour change is advancing fast and it is likely that much will be learned that can be applied to the alcohol field. A question worth addressing is whether there are non-specific generic factors that have a greater impact than the problem specific techniques. For example, do interventions that promote psychological variables such as self-efficacy, mood or motivation generalise to, or support, health targets such as drinking, exercise or smoking. Furthermore, could "nudge theory" and behavioural economics have something to offer that would enhance digital SBIs? It is already the case that the UK government's Behavioural Insights Team are developing initiatives to promote wellbeing.

DYD has moved from being print based to a standalone computer to the internet. More recently digital SBIs have been designed for hand held devices and apps. Inevitably the next steps are for them to be hosted in "the cloud" and probably integrated into networks. There will be options for new types of data collection beyond self-report based on "wearables" and miniaturised medical devices. Automatic data collection is

possible from sensors embedded within mobile phones that can be cross referenced and triangulated with users' other online activity from which algorithms could be developed that may have predictive accuracy. Hence, for example, it may be possible to automatically identify patterns of an individual's behaviour that are associated with an increased probability of drinking. This is not mysterious: for example, a person's phone may show that they are near a pub, at a time of day, in a particular mood, with a particular individual who they usually drink with. This information could then be used to trigger an alarm, send a message or another intervention. There is also the potential to develop digital tools that provide personalised interventions drawing on psychological and other individual characteristics. Where these require input and effort from the user then it will be necessary to research how to facilitate transfer between characteristics associated with the use of mobile devices such as speed, multi-tasking, information sharing, and image rather than language-based processing, to a slower more thoughtful environment of sitting quietly with a computer and completing exercises normally found in therapy or education modules.

For some these recent developments may be an "Orwellian" nightmare. For others they are a natural progression of a politically liberal approach to public health. And for some they are a commercial opportunity for exploitation. There is a legitimate public concern and debate about what may happen to personal data, who controls it and how it is interpreted. There are numerous technical challenges to overcome, but development is happening at pace and these are unlikely to delay matters. I hope I have shown in this work that the development of DYD was heavily influenced by contexts and cultures as much as by the internal logic of the step by step development of a single planned and rational approach. The contexts that will shape new developments will not be the same as DYD, but they will need to be understood and transparent.

No matter how strong the evidence for the effectiveness of digital SBIs, they will not be of value to the public unless there is a clear and practical strategy for implementation and deployment. In this work I have given many examples of the complex issues involved – both from my own research and that of colleagues. Close study and honest transparent

accounts of the details and learning from such projects is vital so that practical lessons can be made available to those that follow. Specifically, in this case, different types of knowledge, experience, skill were all required. In chapter one I adopted the Freeman and Sturdy (2014) conceptualisation of different types of knowledge to describe the development of DYD. The current position appears to be that there is now a good body of “inscribed” knowledge; but it is in the other areas that the challenges exist. The “embodied” knowledge of most workers in the alcohol field is located within traditional face-to-face counselling situations and interpersonal factors. I recognise myself how important it is, when sitting with a client, to be sensitive to nuanced and non-verbal communication. These skills do not necessarily transfer directly to blended interventions and new approaches need to be taught. Furthermore, computer programmers and designers cannot be expected to understand the behaviour of the hazardous drinker as they may not have these types of experiences. This is a challenge for all examples of eHealth and digital interventions. A solution would appear to be coproduction of interventions from an early stage of development. This would bring together those with content knowledge, lived experience, technical expertise, front line staff and policy makers. Currently, however, public sector procurement policies and funding streams (primarily research funding) do not allow for this or easily accommodate the multiple iterative cycles of development and openness to innovation required.

Descriptions of the actual and real processes of development, research and deployment may enable the consolidation of “enacted” knowledge that will bring digital SBIs (and other digital interventions) into the public sphere. This may be achieved partly by traditional means such as papers and conference presentations; but the new types of communication could speed this up. Examples are researchers writing blogs, tweeting about recent findings and events or using social media platforms for discussion. In this way successes and failures can be quickly shared and ideas can be available for public scrutiny.

## **Afterword**

Finally, for me, the most satisfying conclusion of the DYD project is that at the time of writing<sup>48</sup> [www.downyourdrink.org](http://www.downyourdrink.org) remains a free to use publicly available website and that last year (2017) there were 842 new registrations. During this period 704 people made at least one return visit and of these 106 recorded over 5 sessions and 36 over 10 sessions indicating regular use of the site. There were also some very frequent users. Nine users recorded over 20 sessions, 4 over 30 and one recorded 61 and another 97 sessions. I trust they are finding it useful!

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48 March 2018

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## Appendices

### Appendix 1

Sample pages from the original printed manual



## THINKING ABOUT YOUR TARGET (contd)

Some of the ways of getting there. A light-hearted look!



### 1. The Nibbler

"I'll come down by 10 units, then by another 5 and another 5, then by another 10... I'll get there. (If I don't get bored on the way!)"



### 2. The Plummeter

"I'll cut the drink out completely for a few days then let it work back to my target. (If I can stop it drinking further!)"



### 3. The Waverer

"Well, I don't really know. It'll drop 10 units and if I don't like it come back up again. Then, well, I'll say again and come a bit further. (If I don't drink up again!)"



### 4. The Decider

"This is simple. Choose the target and stick. (If I decide to go back up later, that is my decision!)"



### 5. The Non-Starter

NO COMMENT

Seriously though, it is worth thinking about the sort of person you are and which way of working towards your target would suit you best. It is often very helpful to ask someone who knows you well. They may be able to point out which way would be best for you. They would also be able to give you help and support when you actually try it in a week or two. Think about it.

## OF COURSE!

## Appendix 2

### Examples of the first interactive version (DYD<sub>1</sub>)

Screenshot of the home page with a link to the FAST screening questionnaire



An example of the “mouseover” – a technique to engage the user in actively searching



## Appendix 3

### Sample Press Releases and publicity materials



#### **"Down Your Drink" the revolutionary new web-site for problem drinkers aims to tackle heavy drinking**



**in only 6 weeks!**

**SCOTLAND - October 13<sup>th</sup> 2001**

The Alcohol Education and Research Council (AERC) is pleased to announce the launch of "Down Your Drink" ( [www.downyourdrink.org.uk](http://www.downyourdrink.org.uk)) at its annual conference in Edinburgh on October 13<sup>th</sup> 2001. Down Your Drink is a revolutionary, new interactive online program, to help problem drinkers bring their drinking down to safer levels in only six weeks.

A heavy drinking lifestyle causes a whole range of health, personal, social or work-related problems. There are problem drinkers right across the population, but in particular we have identified academics, doctors, health professionals, lawyers, accountants, journalists, farmers, musicians and IT professionals, as "high risk" groups, currently working long hours and experiencing high levels of stress who may turn to alcohol for support. There are also many people at home and alone who use alcohol excessively.

**"With more than 16 million people now surfing the net in the UK, we are convinced that there significant numbers amongst these groups who are found too often in front of a PC with a glass in one hand and a mouse in the other."** said Stuart Linke the Clinical Psychologist behind the development of Down Your Drink.

Problem drinkers are often reluctant to seek help from others, the objective in developing the Down Your Drink web-site, is to provide them with an easy to use, engaging and informative, on line program, accessible 24 hours a day from any PC connected to the internet. The program is **free of charge** and available to anyone who wishes to try to reduce their drinking. Before, joining the program, visitors are asked a few revealing test questions and are immediately fed back their "personal drinking score", identifying whether they have reason to be worried by the level of their drinking.

To ensure confidentiality, the site is fully encrypted and securely hosted with members choosing their own alias user name just for the program.

The early user trials of Down Your Drink are very encouraging. Some problem drinkers say they prefer to click through the web pages than talk to their doctor or an alcohol counsellor. The web site has been designed to be a neutral, self-help interactive program, packed with useful information, placing the user firmly in control of their surfing experience. Program members, set their own targets, decide when and where to complete the program and receive individual feedback. Information is provided without preaching. There are even opportunities for users to take a break at their very own "Cyber Saloon". Here, they can chat with other members of the program, take a look at the league table to see how well others are doing or maybe just read the Joke of the Day or play a game.

Each week, members are asked to complete their Drinking diary, which includes a built in calculator (the "Drinking Genie") which automatically calculates alcohol consumption and expenditure on drink. Progress in reducing drinking level, can easily be compared to the targets they have set themselves early in the program. By the end of the six-week program, members should have reduced their drinking and have learned how to keep it at a safe level.

The potential benefits of the Down Your Drink web site are enormous. It is readily accessible to problem drinkers who are often reluctant to seek help from others. It is also a free online resource for doctors and health professionals to recommend to their patients. For patients who do not have their own access to the internet or are unfamiliar with PC's, doctors may wish to provide supervised access for patients themselves within their own practices.

## GP Bulletin

### Some Problem Drinkers Prefer To “Down their Drink” Online Than See A Doctor.

In the UK, it is estimated that 27% of men and 13% of women currently exceed sensible drinking levels and are at risk of becoming “problem drinkers”. These are people whose heavy drinking lifestyle may be causing them a whole range of health, social or work-related problems.

When problem drinking is identified, usually at a health check or a health screening, up until now the traditional treatment options have been limited to counselling from either their doctor or an alcohol counsellor. For many problem drinkers, the prospect of discussing their private drink problem with anyone is often deeply unappealing and not taken up. For them an effective self-help alternative may be more attractive and present a better chance of success.

On October 13th [www.downyourdrink.org](http://www.downyourdrink.org) - a new online self-help program, for anyone who is concerned by their drinking, will be launched at the Alcohol Education and Research Council Annual Seminar. The “Down Your Drink” web-site provides an interactive program which aims to help problem drinkers develop safer drinking habits. The web-site is confidential, free of charge and accessible 24 hours a day from any PC connected to the Internet. The course is based on the latest, proven practical methods to reduce drinking as recommended by leaders in the field and takes less than an hour a week for only six weeks.

The site is easy to use, engaging and informative. Program members are placed firmly in control of their surfing experience, they set their own drinking targets, decide when and where to complete the program and receive individual feedback. Importantly, information is provided in a neutral way without “preaching” (this can be a real turn off for drinkers) and to ensure confidentiality members choose their own alias user name just for the program and are not required to surrender their private personal details.

The early user trials of Down Your Drink are very encouraging, indicating that many problem drinkers prefer to remain anonymous and click through the web pages than talk to their doctor or an alcohol counsellor. Patients particularly liked the self assessment questionnaires, the “drinking genie” which calculates alcohol consumption and expenditure on drink automatically, as well as the light-hearted “Cyber Saloon” where members can take a well-deserved break from the program.

The program has been developed by Clinical Psychologist Stuart Linke and Dr. Paul Wallace, Professor of Primary Care - a leading specialist in the use of telecommunications for delivering new modes of healthcare. The web-site is fully funded by the Alcohol Education and Research Council.

With more than 16 million people now surfing the net, the developers of Down Your Drink are convinced, there are large numbers of problem drinkers who surf the net regularly all too often with a glass in one hand and the mouse in the other. For patients who do not have their own access to the Internet or are unfamiliar with PC's doctors may wish to provide supervised access themselves within their own practices.

With the increasing popularity of web-sites like NHS Direct, it is hoped that doctors will add [www.downyourdrink.org](http://www.downyourdrink.org) to their list of web-sites they wish to recommend to patients.

For more information about the Down Your Drink self-help program visit the web-site. To obtain leaflets about the programme: Telephone: 0207 530 2378 or email: [info@downyourdrink.org](mailto:info@downyourdrink.org)



Fifty thousand of these leaflets were distributed as inserts in GP publications

**The Revolutionary New Online Program to Help Problem Drinkers**

http://www.downyourdrink.org

**Down Your Drink ....It takes less than an hour a week**

**DOWN YOUR DRINK**

**Should your drinking worry you?**

DOWN YOUR DRINK is the revolutionary six week online program that tells you what you need to know to stay drinking at a safer level. [Click here](#) for more information.

If you think you may be drinking more than is good for you [click here](#) to find out

**If you think you may be drinking more than is good for you visit the website to find out.**

**★ The Down Your Drink self-help program is:**

- ✓ For anyone who is worried by their drinking and wishes to cut down
- ✓ Strictly confidential and free of charge
- ✓ In 6 weekly parts, taking less than an hour a week
- ✓ Accessible 24 hours a day from any PC connected to the Internet
- ✓ Based on the latest, proven practical methods to reduce drinking as recommended by leaders in the alcohol treatment and education field.

**If you know anyone who could benefit from learning how to become "Thinker Drinkers" pass on our web address:**

**www.downyourdrink.org**

To receive additional Down Your Drink leaflets  
tel: 0207 530 2378 e-mail: [info@downyourdrink.org](mailto:info@downyourdrink.org)

**NHS** **aerc** **UCL**



## **Appendix 4**

### The Content of DYD<sub>1</sub>

#### Week 1.

Welcome & Introduction

What drink may do to you (effects on the body)

How to measure drinking (units of alcohol) & keep a diary

Gains and losses from drinking

How much do you know about alcohol quiz?

#### Week 2

Thinking about your target

“Bad thoughts” and “good thoughts”

Helpful thoughts

Thinking drinking

#### Week 3

Blood Alcohol Levels (B.A.L. calculator)

Drink more and drink less triggers

Pros and cons of cutting down

Setting a target and planning to achieve it

#### Week 4

Withdrawal symptoms

How not to drink or how to drink less

Rewards & penalties

Snakes and ladders

## Week 5

Relaxation training

Realistic thoughts

Coping with fears

Alternatives to drinking

Coping with relapses

## Week 6

Staying down

Thinker drinkers

Coping with sleep problems

What have I learned & what have I gained?

Getting support for yourself

What next?

Feedback questions and instructions about the evaluation

Questionnaires

The website includes numerous features that were fully interactive and required an active response from the user. These functions were some of the key ways in which the users were engaged with the programme. All personal responses on the programme were stored within a secure area of the site and accessible only by password. Users could give their own usual email address or choose a new one for the purpose of the programme (via a link to a webmail service provider). Users were also required to choose their own unique, confidential password.

### 1. Drinking Diary

Throughout the programme users were requested to keep a record of their drinking. Although this was not programmed as a compulsory element it was highly encouraged and presented as one of the most important tools for self-

change. The diary was available in the form of a retrospective time-line so that users were asked to complete the diary for the current day first of all and then for the previous day and so on, going back through the previous week. The diary had a number of intelligent features. It “remembered” users’ favourite drinks (recorded at registration and subsequently modifiable), calculated the weekly total of units consumed and estimated the amount of expenditure on alcohol during the week. Users could see a graph on screen of their weekly consumption and compare this to their chosen target if they had entered one. The diary could be printed if required

## 2. Thinking Drinking Log

The “thinking drinking log” was a record of all the users’ responses to quizzes, cognitive behavioural exercises and charts and any notes for themselves that they had recorded during the programme. The log could be viewed on screen or printed off.

## 3. Automated Emails

Users received an email reminder to their private email address if they failed to log on and complete a week of the programme. Users also received daily “drinking tips” via email.

## 4. Preferences

Users were able to control certain aspects of the way in which they interacted with the programme. On the preferences page they could “turn off” either of the automated email function (reminders and “tips”) or change their drinkin preferences.

## 5. Timed Lock Out

The programme automatically recorded the date users completed each stage of the programme. Users were able to visit the programme weekly and although

they could not start the next week's programme until seven days had elapsed, they could look back at previous week's material.

#### 6. The Cybersaloon

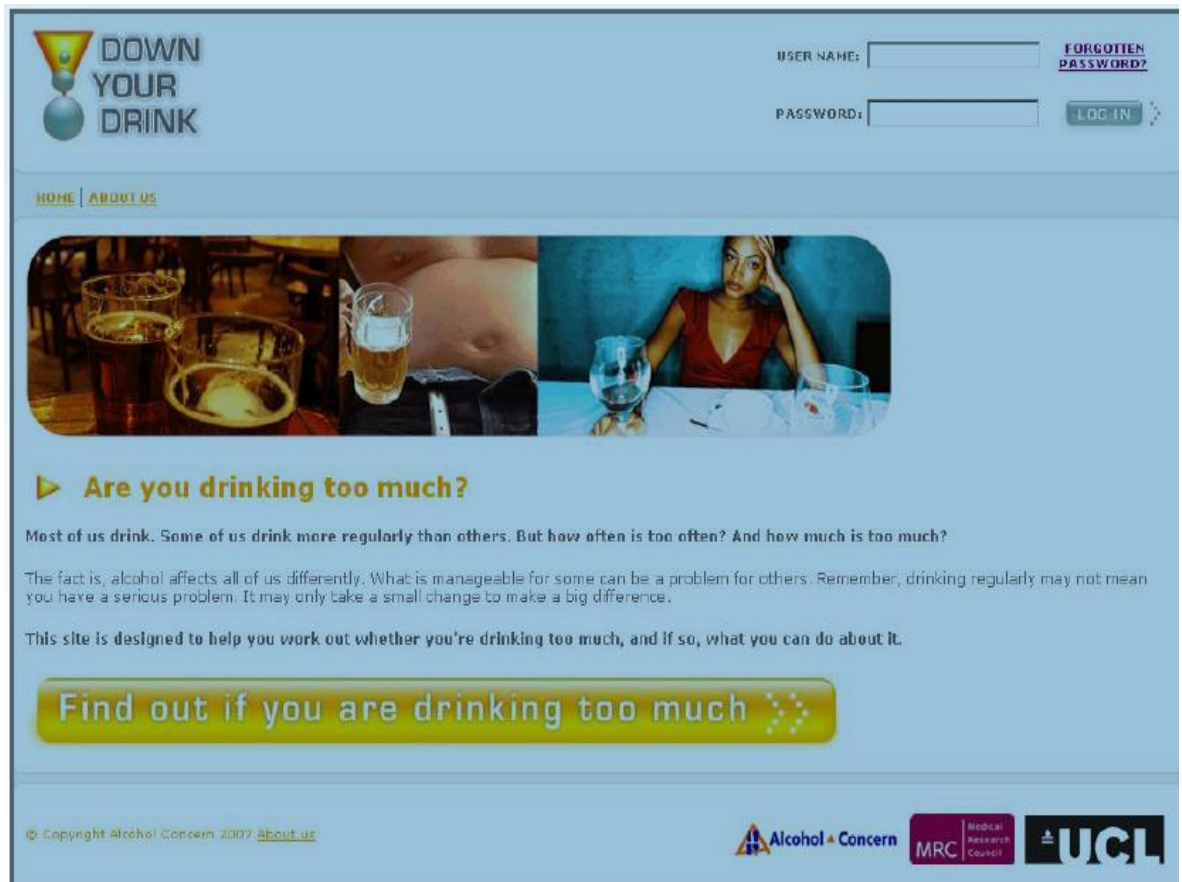
The "cybersaloon" was a section of the website that could be entered at any point during the week. Its purpose was to develop a sense of community among the users of "Down Your Drink". In the saloon were a selection of alcohol related jokes, computer games that could be downloaded and a web board. The web board was a forum where users of the programme could send messages to each other and also send messages to the researchers. Messages could be seen by anyone who had registered with the programme.

#### 7. Email Discussion Group and "chat room"

An email "list" and a "chat room" was developed alongside the web board to facilitate communication between users of "Down Your Drink".

## Appendix 5

Home Page of the “psychologically enhanced” version used in the trial



## Appendix 6

### The Current Homepage of Down Your Drink



## Appendix 7

### HeLP Alcohol (DYD4)

#### Home Page



The screenshot shows the HeLP Alcohol (DYD4) Home Page. The header features the HeLP Alcohol logo and a navigation bar with links: Home, Welcome, Tools, Resources, Drinking Diary, My Record, My Account, and Log Out. Below the header is a progress bar with tabs for Part 1 (Thinking about alcohol), Part 2 (Preparing for & making the change), Part 3 (Overcoming Obstacles), Part 4 (Keeping on Track), Part 5 (Embedding the Change), Part 6 (Planning ahead), and Other Peoples Stories. The main content area includes a search bar, a welcome message, and several interactive sections: 'Calculator: How much did you drink last week?', 'Keep track with a drinking diary', 'Relationships and drinking: see the connections', 'How does Alcohol affect my health?', and 'Ready to cut down? Make a plan you can stick to'. There are also sections for 'My recent drinking', 'Progress', 'Upcoming drinking', and 'My relationships'. The footer contains links for About, Privacy, Contact Us, and Site Map, along with the NHS and UCL logos and copyright information.

**HeLP Alcohol**

Home Welcome Tools Resources Drinking Diary My Record My Account Log Out

Part 1 Thinking about alcohol Part 2 Preparing for & making the change Part 3 Overcoming Obstacles Part 4 Keeping on Track Part 5 Embedding the Change Part 6 Planning ahead Other Peoples Stories

Search

## Welcome to HeLP-Alcohol

Helping you make decisions about your drinking

Many of us drink too much alcohol. Whether you're not sure if need to cut back, or if drinking is a real problem, HeLP-Alcohol has the information and tools to help you look more closely at your drinking. [Read more...](#)

[Go to the last page you visited \(Home\)](#)

**Tip of the day:** Replace some of your alcoholic drinks with a low alcohol drink or non-alcoholic drink (a 'spacer' rather than a 'chaser')- Start drinking later in the day/evening

**My recent drinking**  
No recent drinking  
[Go to drinking diary >](#)

**Progress**  
The last page you viewed was Home

**Upcoming drinking**  
No upcoming events  
[Manage upcoming drinking diary events >](#)

**My relationships**

Name	Age	Sex	Relationship	Drinking
John	51-60 years	Male	Partner	Drinking
David	6-10 years	Male	Friend	Drinking
Emma	11-20 years	Female	Friend	Drinking
John	21-30 years	Male	Friend	Drinking
John	31-40 years	Male	Friend	Drinking
John	41-50 years	Male	Friend	Drinking

[Show my relationships >](#)

About Privacy Contact Us Site Map

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## Example of a Case Study

**HeLP**  
Alcohol

HomeWelcomeToolsResourcesDrinking DiaryMy ForecastMy AccountLog Out

Part 1Thinking about alcoholPart 2Preparing for & making the changePart 3Overcoming obstaclesPart 4Keeping on TrackPart 5Embedding the ChangePart 6Planning aheadOther Peoples Stories

Search

You are here: / Home / Other Peoples Stories / Kate / Part 1

Other Peoples Stories

Home  
Steve - Steve's alcohol journey  
Sian - A story about risk  
Jim  
**Kate - Alcohol and health**  
Rob - Rob's lonely life  
Judy  
Ken  
Julie  
Kate  
Jane  
Dr Jenkins  
Kevin  
Joe  
Ras  
Marie


Recently visited

less than a minute ago  
Part 1  
less than a minute ago  
Home

Kate - alcohol and health

Part 1

**Alcohol Awareness Case Study : Kate's Story**



There are no upper age restrictions on drinking a lot. In fact older people are drinking heavily as much as anyone else. Online supermarket shopping means that alcohol can be delivered right to the front door.

Kate enjoyed a drink. And there was no reason why she shouldn't? Kate had had a hard life and at eighty three she deserved a bit of relaxation. Her son and daughter had families of their own and they were all OK. She'd lived alone since her husband had finally left her fifteen years ago and as far as she was concerned it was good riddance. He had been a waste of space and drank far too much. Kate had a glass of beer every night and then a couple of large glasses of whiskey before going to bed. She'd wanted some pills to help her sleep, but her doctor had warned her not to mix pills with alcohol and she had preferred the whiskey. She hadn't originally gone to the doctor to talk about her sleep though. It was her digestion that had worried her, along with general aches and pains. The doctor had done a few tests which had proved negative and that had been that. When Kate had mentioned how much alcohol she had been drinking the doctor had said nothing about it — so Kate had assumed it was OK and carried on as before...

Is Kate's alcohol consumption putting her at risk? Was the doctor right not to mention anything?

Kate is very worried that without a drink she won't be able to sleep. And there is no-one encouraging her to cut out the night time drink and, in fact, there is no-one actually noticing that she is drinking at all! Kate needs a proper chat with her doctor. The place to start is with some clear two-way communication. Then she can make a plan and set herself some limits. She may need to switch a few things such as alcohol and tablets until she gets it right.

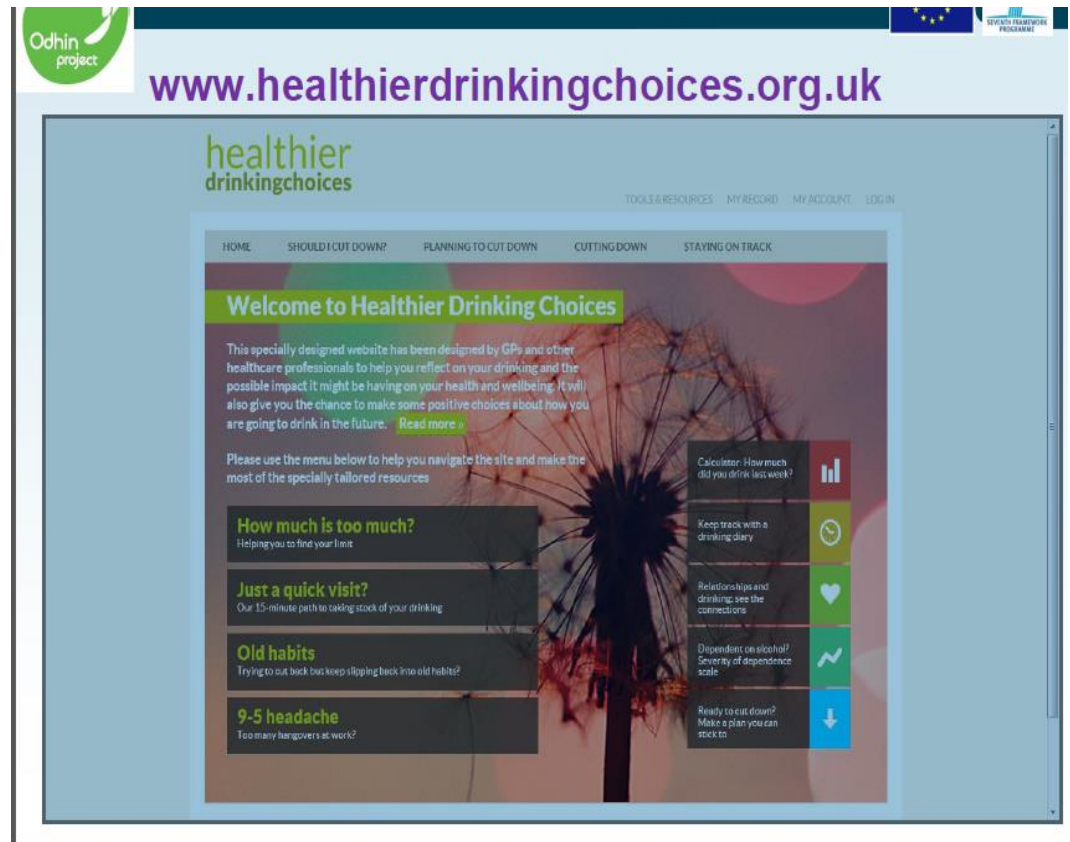
Previous

Next



## Appendix 8

### Healthier Drinking Choices UK and Australia



## Appendix 9

### Drinking Choices for Better Mental Health



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